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What Price Imitation? . . . . . .

Import Control Under Federal Laws . . . . . .

The Practical Impact of Proposed Uniform Commercial Code on Food Poisoning Cases . . . . . .

Rodent and Insect Infestation in Wheat and Flour

Development of New Drugs . . . . . .

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The monthly FOOD DRUG COSMETIC LAW JOURNAL succeeds the FOOD DRUG COSMETIC LAW QUARTERLY and continues its editorial policy. That policy is to record the progress of this law and to provide a constructive discussion of it, according to the highest professional standards. The QUARTERLY, established in March, 1946, was the original publication on this law. The JOURNAL, instituted in March, 1950, is the only forum for current discussion of this law and it renders an important public service. For it is an invaluable means (1) to create a better knowledge and understanding of this law, (2) to promote its due operation and development, and (3) thus to effectuate its great remedial purposes. In short: while this law receives normal legal, administrative, and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; and the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

F. K. Killingsworth, who brings us up-to-date on the developments in import control under Federal law since 1947 in this issue of the *Journal,* has a close-up view of the situation, as he is Assistant Chief of the New York District of the Food and Drug Administration, in charge of import operations.

Born in Columbia, South Carolina, he received both his Bachelor's and Master's degrees in chemistry from the University of South Carolina, and did additional post-graduate work in chemistry at the University of Maryland. In addition, Mr. Killingsworth possesses an LL.B. degree from the University of Maryland, and is a member of the Bar of the State of Maryland.

During the depression, in 1933 and 1934, he was a Civilian Conservation Corps educational advisor. He began work with the Food and Drug Administration as a junior chemist in 1935, and was advanced to his present position in 1945.

A paper submitted during the course of the recent food law program at the New York University School of Law is the cause of **William J. Condon's** being one of the newest—and youngest—contributors to the *Journal.* Born thirty years ago in Whitman, Massachusetts, he "did nothing of moment except to grow for the next twenty years." His education, which was interrupted by four years in the United States Coast Guard, began with an A.B. degree from Boston College, continued with an LL.B. degree from Boston College Law School, and ended, only temporarily, with the degree of Master of Laws from the Harvard Law School. In 1947, he joined the staff of the General Attorney of Swift & Company in its New York City office, where he has remained up to the present time.

"I have spent practically my whole adult life in food and drug work," says **J. O. Clarke,** Director of Program Research in the Food and Drug Administration. After his graduation from the Georgia School of Technology in 1913, he was Assistant State Chemist of Georgia for several years. In 1917, he entered the Bureau of Chemistry, which subsequently became the Food and Drug Administration. In his work with the Administration, Mr. Clarke has been located in Savannah, Georgia, New York, Chicago, and for the past two years in Washington, D. C.

The Medical Director of the Food and Drug Administration, **Dr. Erwin E. Nelson,** still thinks of himself as a teacher due to his academic background and career. A Missourian, who holds the Ph.D. degree from the University of Missouri and an M.D. degree from the University of Michigan, he taught pharmacology—his field of special interest and training—for many years in the Medical School of the University of

Michigan, and later at Tulane Medical School. He still gives an occasional lecture at George Washington Medical School.

During 1935 and 1936, while on leave from the University of Michigan, he organized the Division of Pharmacology of the Food and Drug Administration and acted as its chief. In 1947, Dr. Nelson returned to the Food and Drug Administration as Chief of the New Drug Section of the Division of Medicine; he has been Medical Director since January, 1950. In addition, he served as a member of the *United States Pharmacopoeia* Revision Committee for the XI, XII, and XIII Revisions.

At twenty-one years of age, **George P. Larrick** became a Federal Food and Drug Inspector in Cincinnati, Ohio. He has had no other occupation since, although his extra-curricular activities have been enlarged to include a family of four children—three boys and a girl—and a small water-front farm where fishing is a frequent pastime.

Mr. Larrick has come up through the ranks to his present position as Associate Commissioner to which he was appointed in 1948. Since his first appointment, in 1923, after graduation from Ohio State University, he was subsequently appointed Junior Administrative Assistant in 1928, Administrative Assistant in 1929, Senior Food and Drug Inspector in 1930, Chief Food and Drug Inspector in 1939, and Assistant Commissioner in 1945.

He was among the initial contributors to the *Food Drug Cosmetic Law Quarterly* in 1946; his articles have appeared therein on several occasions during the intervening years.

Winton B. Rankin, another member of the Food and Drug Administration, is Assistant Director of Field Operations. He holds Bachelor of Science degrees in the fields of mathematics, science, and pharmacy, and a Master of Science degree in agricultural chemistry as well as being a licensed pharmacist in the State of North Carolina.

After several years as teaching fellow at the College of Pharmacy, Ferris Institute, and brief employment in the retail drug business in North Carolina, Mr. Rankin joined the Food and Drug Administration, in 1939, as a Seafood Inspector on the south Atlantic coast. Since then, he has been Resident Inspector, Assistant to the Chief of the Eastern District, Chief Inspector, and Acting Chief of the Interstate Division, before he assumed his present position in the fall of 1948.

In Congress

Amendment of Food, Drug, and Cosmetic Act.—Consideration of two proposals to amend the Federal Food, Drug, and Cosmetic Act has been urged by the Senate Committee on Agriculture and Forestry in a report submitted March 29 pursuant to S. Res. 36. S. 2432 would require a minimum fat content for bread, and S. 2540 would require the labeling of bread or rolls. Both bills are in the Senate Committee on Interstate and Foreign Commerce.

Frozen Fish Standards.—A bill (H. R. 7441) to promote the development and improvement of standards for frozen fishery products and to provide for the voluntary grading, inspection, and certification of such products is in the House Committee on Merchant Marine and Fisheries.

Narcotics.—On March 28, two narcotic bills were presented and referred to the House Committee on Ways and Means: H. R. 7891 to amend Section 3224 (b) of the Internal Revenue Code, relating to the transportation of narcotics; H. R. 7892 relating to the definition of the term "contraband article" in the case of narcotic drugs, as used in the Act of August 9, 1939.

Sherman Act Penalties.—An increase in Sherman Act penalties designed to raise the fine limit to the point where it will no longer be "so low that violation is regarded . . . as a good business risk" was recommended to the House of Representatives when the Judiciary committee reported out H. R. 7827. The fine would be raised from $5,000 to $50,000.

The bill as reported by the committee on April 6 makes no change in the jail term available as a penalty in the antitrust law, but after commenting that in the one instance where such sentences were imposed, they were suspended, the comittee in its report recommended that wider use be made of the imprisonment provision in repeated and flagrant cases.

Another bill, H. R. 6679, also considered by the Judiciary committee, would also have increased penalties in the Clayton and Robinson-Patman Acts, but after decision to omit changes in those acts, the bill was replaced by H. R. 7827.

Investigation of Oleomargarine Industry.—An investigation of principal oleomargarine manufacturing firms to determine whether the antitrust laws are being violated was favored in Senate Concurrent Resolution 86 introduced April 26, 1950, and referred to the Senate Committee on Judiciary.

Import Controls Over Fats, Oils, and Rice.—A bill (S. 3382), introduced April 10, 1950, to continue certain powers, authority, and discretion to exercise, administer, and enforce import controls with respect to fats and oils (including butter), and rice and rice products was approved by the Senate Banking and Currency Committee on May 5, and was ordered reported and amended. A new bill, S. 3550, was introduced and reported to reflect committee amendments.

Corn and Wheat Excess Marketing Penalty.—The rate of penalty in the farm marketing excess of corn and wheat as appears in Public Law 74, Seventy-seventh Congress, would be amended by S. 3510 which was introduced April 28, 1950 and referred to the Senate Committee on Agriculture and Forestry.

Development of Marketing Facilities for Perishable Agricultural Commodities.—The improvement and development of marketing facilities for handling perishable agricultural commodities is to be encouraged by Federal assistance under H. R. 8320, H. R. 8378, and H. R. 8485, which were introduced and referred to the House Committee on Agriculture.

Import Quotas on Agricultural Commodities.—The imposition of import quotas on agricultural commodities when imports of such commodities tend to interfere with price support or other programs administered by the Department of Agriculture is provided for in H. R. 8231 which would amend Section 22 of the Agricultural Adjustment Act. The bill was introduced on April 26, 1950, and was referred to the House Committee on Agriculture.

In the Department of Agriculture

Revision of Frozen Broccoli Standards.—A scoring system for ascertaining grade with requirements of color, uniformity of size, absence of defects, and character has been included in a second issue of grade standards as proposed by the Department of Agriculture. Tolerances for certification of officially drawn samples are provided. Data, views, or arguments in regard to the proposed revision should be filed with the Chief, Processed Products Standardization and Inspection Division, Fruit and Vegetable Branch, Production and Marketing Administration, not after May 20, 1950 (15 F. R. 2219).

Revision of U. S. Standards for Beans.—The standards for beans, as recently revised, established the following classes of beans: pea, medium white, marrow, great northern, small white, flat small white, large white, white kidney, light red kidney, dark red kidney, western red kidney, yelloweye, old fashioned yelloweye, small red, pink, bayo, mung, blackeye, cranberry, pinto, large lima, baby lima, miscellaneous lima, miscellaneous, and mixed. Grades are the numerical grades, substandard grades, sample grades, and special grades. Splits, damage, foreign material, stones, weevil infestation, screening, and defects such as broken, blistered, or wrinkled beans are factors to be considered in grading (15 F. R. 2175).

Certified Products for Dogs and Cats.—Amendatory provisions for inspection, certification, and identification as to class, quality, quantity, and conditions of canned or fresh frozen 32 per cent component of a maintenance food for dogs, cats, and other animals have been incorporated into the regulations issued under the Farm Products Inspection Act by the Secretary of Agriculture. Admonitory provisions against alteration or imitation of the statements of certification have been added. An inspection service is available to persons requesting it (15 F. R. 2077).

Revision of Canned Apple Juice Standards.—Revision of existing grade standards for canned apple juice has been proposed by the Department of Agriculture. A scoring system to aid in establishing grades based on factors such as color and absence of defects is included (15 F. R. 1844).

In the Food and Drug Administration

Labeling of Oleomargarine.—Labeling requirements for colored oleomargarine under the Federal Food, Drug, and Cosmetic Act, as recently amended, are clarified in regard to use of the words "margarine" and "oleomargarine," label statements as to ingredients, artificial colors, artificial flavors, vitamins, preservatives, and emulsifiers, and type sizes for the letters used in labeling (Statement of General Policy or Interpretation by John L. Thurston, Acting Administrator. April 10, 1950. 15 F. R. 2081).

Customs Bonds.—When the collector of customs determines, with the advice of the appropriate District Chief of the Food and Drug Administration, that the amount of any bond is not a sufficient deterrent to default with respect to products subject to the Federal Food, Drug, and Cosmetic Act, in accordance with a recent amendment of

Customs Regulations, he may require an additional bond of an amount and with such conditions as the Food and Drug Administration recommends to apply to particular importations or classes of importations (15 F. R. 796).

Certification of New Antibiotic-Containing Drug.—Certification of a new streptomycin product, dihydrostreptomycin sulfate solution (crystalline dihydrostreptomycin sulfate solution) has been provided for in an amendment to the regulations for certification of batches of antibiotic and antibiotic-containing drugs. Tests and methods of assay for the new product are also provided for in the amendment (15 F. R. 2082).

Sheep and Goat Bile.—Bile from the condemned livers of slaughtered sheep and goats may be released for use in the manufacture of certain drugs as in a previous notice concerning ox bile (15 F. R. 1303), except that the words "Sheep Bile" or "Goat Bile," as the case may be, shall be substituted for the words "Ox Bile" upon the label. In the case of mixtures of bile from any two or all three of the sources mentioned, the label shall indicate the sources of such bile (Statement of General Policy or Interpretation by John L. Thurston, Acting Administrator. April 24, 1950. 15 F. R. 2436).

Canned Corn Standards.—Standards of identity, quality, and fill of container for canned corn were the subject of a tentative order incorporating findings of fact and proposed amendments which was issued by the Federal Security Administrator. All references to white corn, white sweet corn, white sugar corn, yellow corn, yellow sweet corn, yellow sugar corn, golden corn, golden sweet corn, golden sugar corn, and golden field corn would be deleted from the regulations to establish standards for corn and field corn. Standards of identity and fill of container are established for canned field corn as well as for sweet corn, but no standard of fill is proposed for whole-kernel and evaporated corn due to insufficient evidence. Written exceptions to the tentative order will be accepted for filing until June 5, 1950, from persons whose appearances were filed at the hearing on the proposed rules on March 15, 1949 (15 F. R. 2060; 15 F. R. 2425).

Pineapple Standards Hearing Postponed.—A hearing called upon proposals by the Pineapple Research Institute of Hawaii, which represents a substantial portion of the pineapple canning industry, to adopt definitions and standards of identity, standards of quality, and standards of fill of container for canned pineapple and canned pineapple juice has been postponed. The date of the hearing has been changed from October 16, 1950, to October 15, 1951 (15 F. R. 2201).

Tea Standards.—Standards for tea shipped from abroad on or after May 1, 1950, have been established in an amendment to regulations promulgated under the Tea Importation Act. Standards will be: (1) Formosa Oolong, (2) Congou, (3) India, (4) Formosa Black (to be used for Formosa and Japan Blacks), (5) Japan Green, (6) Gunpowder, (7) Scented Canton, and (8) Canton Oolong. Standards for tolerance for dust and siftings in all teas have also been amended (15 F. R. 2084).

Vegetable Fat in Ice Cream.—Frozen products made in semblance of ice cream, but containing vegetable fats in complete or partial substitution for milk fat, are regarded as adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, and are therefore subject to action under the law (Statement of General Policy or Interpretation by Oscar R. Ewing, Federal Security Administrator. April 6, 1950. 15 F. R. 2082).

New Chief of Buffalo District.—Allen T. Retzlaff, formerly Chief of the Balti-

more district, is now Chief of the Buffalo district replacing W. H. Heath, deceased. John W. Sanders, Jr., formerly Chief Chemist at Philadelphia, has been appointed Chief of the Baltimore district.

Notices of Judgment.—The Federal Security Agency has issued the following Notices of Judgment under the Federal Food, Drug, and Cosmetic Act recently: Foods Nos. 14901-14950, 14951-15000, issued March 1950, 15001-15050, 15051-15100, 15101-15150, issued April 1950; Drugs and Devices Nos. 2771-2790, 2791-2810, issued February 1950, 2811-2830, 2831-2850, issued March 1950, 2851-2870, 2871-2890, 2891-2910, issued April 1950.

In the Federal Trade Commission

Medicinal Preparations.—Misleading advertising of a product as an adequate and effective cure and treatment for arthritis, bursitis, neuritis, and sciatica is charged in FTC Docket 5741. "The relief afforded will be limited to such a degree of temporary and partial analgesic and antipyretic effects as its aspirin content may afford in the individual cases," the Commission states. The complaint lists toxic effects, such as deafness and nausea, which may result if the preparation is taken for a prolonged period in larger doses than specifically mentioned in the directions.

An advertised cure or treatment for arthritis or its manifestations including pain, soreness, and stiffness is challenged in FTC Docket 5746. Additional therapeutic representations of cure of "athelete's foot," boils, and acne are also questioned.

Representations that a medicinal product is an effective treatment or remedy for arthritis, sciatica, or neuritis or that its use will arrest their progress was ordered to be ceased in FTC Docket 5663 as actual benefits from the preparation are limited to temporarily relieving pain in the area immediately surrounding the point of injection.

The advertising of Antiphlogistine as a "medicated poultice" supplying moist heat for several hours and hence being an effective treatment for chest colds, bronchial irritation, aching muscles due to sprains, and similar conditions is challenged in FTC Docket 5755. The complaint alleges that none of the medicinal ingredients in the preparation are in sufficient amount to produce any therapeutic effects and that it actually may act as a "direct irritant" and delay normal healing processes when used on burns or skin irritations.

A company producing a vitamin and iron preparation has agreed to discontinue unqualified representations as to the efficacy of its product in the treatment of mineral or vitamin deficiency symptoms and to limit its claim to cases where the symptoms are due to an iron deficiency or to a deficiency of Vitamin B-1 (Stipulation 7964).

Representations that a medicinal product is of value in the treatment of aches, stiffness, flatulence, heartburn, biliousness, poor appetite, poor digestion or complexion or that it will prevent colds or relieve constipation are to be ceased by agreement (Stipulation 7970).

False and misleading advertising claims for an antihistamine preparation, Inhiston, are alleged in FTC Docket 5763. The complaint charges that the drug is not a competent or effective treatment for either the prevention or control of colds, and that it may even be unsafe and result in injury or harm to the

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WHAT PRICE IMITATION?

BY EDWARD BROWN WILLIAMS

DOES the Federal Food, Drug, and Cosmetic Act [1] bar some foods from interstate commerce solely because they are imitations of or substitutes for other foods?

The pertinency of this question and the practical necessity of an answer to it become increasingly evident as the trend of judicial proceedings directed at such products unfolds against the background of the developing policy of the Food and Drug Administration. An affirmative answer would constitute an explicit warning to food manufacturers and processors that investment in such foods for marketing in interstate commerce, whatever may be their merits of economy or nutrition, would indeed be a hazardous undertaking.

Unfortunately categorical reply is not possible. Nor it is to be supposed that official plans have been fully charted through the maze of legal and economic considerations which bear upon the problem. But policy formation is sufficiently advanced to indicate that its course is toward a drastic limitation on the shipment of imitation and substitute food products.

[1] 21 U. S. C. 301. References to the Act which follow are to section numbers as enacted (Public Law No. 717, Seventy-fifth Congress, Third Session, Chapter 675).

MR. WILLIAMS IS A MEMBER OF THE BAR OF THE DISTRICT OF COLUMBIA

There are two classifications of foods against which the developing policy is mirrored: *standardized foods* (those for which definitions and standards of identity have been established by the Federal Security Administrator under Section 401 of the Act [2]) and *unstandardized foods*. The role of the latter is conveniently considered first. It reflects the historical aspect of the entire problem and appears importantly under both the Food and Drugs Act of 1906 [3] and the current statute.

Imitation of Unstandardized Foods—Historical Sketch

Substitute foods and imitations are by no means recent phenomena. They have plagued the Food and Drug Administration since the inception of its regulatory powers in 1906. The *bete noir's* bailiwick has never been completely invested, although determined siege has been laid recurrently. It is now apparent, however, that the new weapon of attack, the Act of 1938, is vastly more effective than the original defective instrument of 1906.

Neither the 1906 Food and Drugs Act nor the present statute defines "imitation" or "substitute." Happily, in an area of such variety, exact definition is not essential to a consideration of the question with which we are here concerned. Accuracy and purpose will be more efficiently served by an empirical study of official policies and of judicial decisions rendered under given statutory conditions. The pertinent practical considerations involved do not center primarily on exact

[2] Section 401: "Whenever in the judgment of the Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity. . . ."

[3] 21 U. S. C. 1 (1934 ed.).

classifications. They depend, rather, upon the operation and effect of administrative policies in the general field of "cheapened" foods and of foods (not necessarily cheapened) in which an ingredient (or ingredients) is used in substitution for natural products or for those of recognized standard composition. It is with this broad field that this discussion will deal.

Under the Act of 1906, the efforts of the Food and Drug Administration in attacking cheapened foods which lent themselves to deceptive practices were largely thwarted by the interpretation lent by some courts to the so-called distinctive name proviso of that Act,[4] and by the absence of standards of identity of legal stature.

The earlier statute declared a food to be misbranded "if it be an imitation of . . . another article,"[5] unless it was plainly labeled as an imitation.[6] The distinctive name proviso exempted from the stigma of misbranding "mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article. . . ."

Varying interpretations were decreed of this somewhat clumsy but reasonably intelligible language,[7] but in such contests as those involving "Hudson's Extract,"[8] "Smack,"[9] and "Bred Spred,"[10] the Administration received set-backs which convinced its officials that more effective protection of the citizenry from the widespread pattern of substitute articles of food was essential. Thus, it was concluded that the distinctive name proviso, so destructive of enforcement efforts, must go; and, of paramount importance, that there must be standards by which to measure compliance or violation with provi-

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[4] Section 10, paragraph *First*, of proviso relating to food.

[5] Section 10, paragraph *First*, relating to food.

[6] Section 10, paragraph *Second*, of proviso relating to food.

[7] Regulation 19 promulgated under the 1906 Act provided: "(b) Mixtures or compounds with distinctive names shall not be imitations of other articles. . . ." *Regulations for the Enforcement of the Federal Food and Drugs Act of June 30, 1906, as amended (Tenth Revision).*

[8] *Hudson Manufacturing Company v. United States*, 192 Fed. 920 (CCA-5; 1912).

[9] *United States v. 24⅓ Gallons of Smack*, Notices of Judgment under Food and Drugs Act, No. 14416 (DC Wis., 1926).

[10] *United States v. 49½ Cases of Bred Spred*, Notices of Judgment under Food and Drugs Act No. 17,351 (1906); White and Gates, *Decisions of Courts under the Federal Food and Drugs Act*, p. 1204. In this case, the court interpreted the proviso as relieving from misbranding "articles not labeled with the distinctive name of another article," apparently without regard to whether they were imitations or labeled as such.

sions of law directed at "economic adulterations," characterized chiefly by substitution of ingredients.

In due course, after considering official documentation and argument exposing the evils of debased foods, a committee of the United States Senate in charge of one of the bills which eventually led to the 1938 Act reported that "the loophole afforded the dishonest manufacturer by the so-called 'distinctive name' proviso of the present law will be closed" [11]; and the same group, after considering a bill providing for legally enforceable definitions and standards of identity, was of the opinion that "the provisions of the present law . . . dealing with . . . the cheapening of foods either through lessening the quantities of valuable constituents or through the addition of cheaper constituents, require definitions and standards whereby the article can be judged." [12] These were provided for in the new law under Section 401.[13]

Throughout, the guiding principles were articulated to the effect that worthy provisions of the existing law were to be preserved, that loopholes for the escape of the unscrupulous were to be rejected, and that additional machinery for the campaign against food debasement was to be provided.

Unstandardized Foods Under the Act of 1938

The underlying difficulty faced by the government under the 1906 Act had been clearly spelled out for a Senate Committee by Mr. Walter G. Campbell, then Commissioner of Food and Drugs. Mr. Campbell pointed out that, when enforcement action depended upon the allegation that a valuable constituent had been removed from a food, or that some ingredient had been substituted, there must be a standard against which to test the alleged removal or substitution. The only means of establishing such a standard was by proving in court "by testimony of manufacturers, and the testimony of housewives, what that standard is." [14]

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[11] Senate Report No. 361, Seventy-fourth Congress, First Session. Dunn, C. W., *Federal Food, Drug, and Cosmetic Act* (1932), p. 247.

[12] Senate Report No. 361, Seventy-fourth Congress, First Session. Dunn, C. W., *Federal Food, Drug, and Cosmetic Act* (1932), p. 245.

[13] See footnote 2.

[14] Hearings before a subcommittee of the Senate Committee on Commerce on S. 1944, Seventy-third Congress, December 7, 1933. Dunn, C. W., *Federal Food, Drug, and Cosmetic Act* (1932), p. 1073.

Under the new law, although this burden of proof is removed for foods standardized under Section 401, it remains for all others. If a food which fails to conform to a standard so established is sold in interstate commerce as the standard article, it is adulterated or misbranded, or both. It may be condemned and its shipper subjected to criminal penalties under the statute.

This proposition is taken as being perfectly sound. The result reached is within the contemplation of the law. It brings us, however, straight to the threshold of an area of doubt in which are encountered both legal and semantic difficulties of some proportions. Suppose, for example, that a substitute product is honestly labeled when shipped in interstate commerce; perhaps with the word "imitation" and the name of the food imitated perhaps with other equally revealing words.

What is wrong with that? The *Poppy Seed* case [15] illustrates the evil which may result, although faking a poppy seed may seem, of itself, a fairly harmless economic pastime.

British India poppy seeds, naturally white, were disguised by appropriate tinting to resemble the more expensive Dutch Blue and Turkish varieties. They were shipped to jobbers only, in bags labeled: "Produce of British India, artificially colored with vegetable colors." The goods were seized as adulterated under the provisions of Section 402(b) (3) and (4) [16] of the Act upon the allegation that the coloring matter concealed inferiority and caused the article to appear better or of greater value than it was.

The circuit court of appeals, in reversing the lower court,[17] held that the goods were adulterated and subject to seizure and condemnation, although they were honestly labeled and honestly invoiced to the jobber. The consumer of rolls and buns decorated with the seeds would not see the labeling, and it is the consumer which the Act seeks to protect, so reasoned the court following the government's argument.

[15] *United States v. Two Bags . . . Poppy Seeds*, 147 F. (2d) 123 (CCA-6; 1945).

[16] Section 402: "A food shall be deemed to be adulterated . . . (b) . . . (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed therewith so as to . . . make it appear better or of greater value than it is." This case involved no allegation of omission of a valuable constituent or of substitution (Section 402 (b) (1) and (2), which are associated with departures from a standard, but it is illustrative of an important principle, often involved in such matters, which will be developed.

[17] 54 F. Supp. 706.

The lower tribunal had considered that the condition of the goods at the time of seizure was controlling and that, being then properly labeled, they were beyond the reach of the statute.

The statutory authority invoked was that language of Section 304(a), which provides for seizure of articles which are adulterated "when introduced into or while in interstate commerce." It would probably not be contended, even today, that interstate commerce itself extends to the restaurant table where the poppy seeds are offered to the unsuspecting diner, or even that the concept reaches the baker's shop where comestibles are garnished with the tinted delicacy. If the label remained attached to the article until the consumer obtained it, it seems doubtful, indeed, that it would be condemned as adulterated. Yet, given the limitation of jurisdiction to an adulteration existing when the food was in interstate commerce, we are impelled to the conclusion that, to the court, the concept of economic adulteration exists entirely apart from labeling.

Other proceedings further define the trend indicated in the *Poppy Seed* opinion. Consider the *Pop'n Oil* seizure.[18] The product was mineral oil, artificially colored and flavored, and shipped in barrels. It was destined for use on popcorn sold in movie houses. Two of the allegations were the same as those made in the *Poppy Seed* case: concealing of inferiority and causing the article to appear better or of greater value than it was, by the addition of color and flavor (Sections 402(b)(3) and (4)).[19] Again, it was alleged that the article was so adulterated "when introduced into or while in interstate commerce." The labeling was truthful. The court nevertheless ordered condemnation. There was a stout dissent in which it was stated that "There was no effort at deceit while in interstate commerce with which alone the Federal Act is concerned." [20]

Here again the Food and Drug Administration's concern was with the purchaser of the popcorn with which the offending oil was to be mixed. The same legal concepts are involved as governed the *Poppy Seed* case.

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[18] *United States v. 36 Drums of Pop'n Oil*, 164 F. (2d) 250 (CCA-5; 1947) [CCH *Food Drug Cosmetic Law Reports* ¶ 7066].

[19] The government did not press, in the court of appeals, a charge of "substitution" under Section 402 (b) (2), and abandoned a misbranding charge under Section 403 (b).

[20] 164 F. (2d) 253.

Under Section 301(b) of the statute, an act is prohibited and criminally cognizable which is committed while a food is held for sale after shipment in interstate commerce, if such act results in the adulteration or misbranding of the food.[21] It is evident that the purpose of this section is to deal with adulterations and misbrandings which do not occur in interstate commerce. If, therefore, the seeds or oil are offered for sale under the name of another food (the Turkish product or vegetable oil), within the meaning of Section 403(b),[22] the act of so offering them would be prohibited under Section 301(k) as one resulting in the misbranding of the food. Moreover, under the present seizure provision (Section 304(a)),[23] such articles, if adulterated or misbranded while being held for sale after shipment in interstate commerce, are subject to seizure and condemnation.

Certain practical difficulties are seen by the Food and Drug Administration in applying such sanctions in cases of this complexion. There would be a decided element of futility in attempting to prosecute numerous vendors of such cheapened foods throughout the United States, with the limitations of staff and budget under which the Administration operates. As for seizure, some element of levity might be created by a government effort to possess itself of the "Pop'n Oil" offered for sale on hot popcorn, or to capture the colored seeds reposing on a bun on the restaurant table, but the practical results would probably be unsatisfactory. A more effective course, therefore, if the law permits, is to proceed against the food in such cases as being adulterated "when introduced into or while in interstate commerce."

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[21] Section 301: "The following acts and the causing thereof are hereby prohibited: . . . (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale *(whether or not the first sale)* after shipment in interstate commerce and results in such article being *adulterated or* misbranded." The underscored words were added by the Miller Amendment, Act of June 24, 1948, Section 1, 62 Stat. 582. The authority to proceed against such acts resulting in *misbranding,* being part of the statute as enacted in 1938, was in effect when the poppy seeds and "Pop'n Oil" were libelled.

[22] Section 403: "A food shall be deemed to be misbranded . . . (b) if it is offered for sale under the name of another food."

[23] Section 304 (a): "Any article of food . . . that is adulterated or misbranded when introduced into or while in interstate commerce *or while held for sale (whether or not the first sale) after shipment in interstate commerce* . . . shall be liable to be proceeded against while in interstate commerce or at any time thereafter. . . .". The underscored portions of the provision were added by the Miller Amendment, Act of June 24, 1948, Section 2, 62 Stat. 582.

The *Salad Dressing* case,[24] a criminal proceeding under Section 301(a) of the Act [25] against the shipper of an unstandardized food, may be cited as instructive. One of the products involved was Beck's salad dressing, "Victory Dressing," which contained mineral oil. It was alleged, among other things, that it was misleading to designate as salad dressing an article composed primarily of mineral oil, since the term "salad dressing" is understood by purchasers to mean vegetable oil dressing, and that the article was adulterated by reason of the substitution of mineral oil for vegetable oil. The substitution charge, which was brought under Section 402(b)(2),[26] depended upon proof of a customary standard for its support. No question of artificial color or flavor was involved, and mineral oil was listed on the label as one of the ingredients of the food.

The defendant was found guilty, but the court clearly implied that, had the label borne a statement prominently displayed in connection with the name of the product stating that it contained mineral oil, the food would have been found to be neither misbranded nor adulterated. If this view should prevail, an article so labeled would, of course, still be open to attack if proof were available to show that it was actually sold as vegetable oil dressing and was, therefore, misbranded as having been offered for sale under the name of another food (Section 403(b)).[27]

As a logical proposition, the result reached by the court seems sound, for reasons which will be developed hereafter. By contrast, to reach the conclusion that the poppy seeds and "Pop'n Oil" were adulterated in interstate commerce, it was necessary for the courts deciding the fate of those articles to ignore the honest labeling denying the authenticity of the products, a step which opens the way to a comprehensive ban upon the interstate marketing of imitation or substitute foods. For if the labeling may be entirely disregarded in

[24] *United States v. Beck* (DC Iowa, 1946) [CCH *Food Drug Cosmetic Law Reports* ¶ 7092].

[25] Section 301: "The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated or misbranded."

[26] Section 402: "A food shall be deemed to be adulterated . . . (b) . . . (2) if any substance has been substituted wholly or in part therefor. . . ."

[27] See *United States v. 55 Cases, etc.*, 62 F. Supp. 843 (DC Ida.; 1943) where the government failed to show to the satisfaction of the court that popped corn, the seized product, was adulterated because it contained mineral oil in lieu of melted butter and vegetable oil, that is, that the customary standard for popped corn, which the government essayed to prove, excluded mineral oil as a proper constituent. The product was artificially colored but that fact was declared on the label and the court found no misbranding.

determining whether there is adulteration in the economic sense, it seems to follow that a showing of consumer deception is not required, even where unstandardized foods are concerned. The cases which have been considered seem to add up to an administrative trend toward such an objective and, as we have seen, some courts have been encouraging to the government. Certain countervailing factors, which perhaps have not been considered by the courts, will be brought out in the discussion of standardized foods.

Standardized Foods—Act of 1938

The test for departure from the standard of foods for which definitions and standards of identity have been prescribed is found in the misbranding section of the Act whereas, as has been noted, the test for unstandardized foods appears, in both the 1906 Act and the present law, in the provisions describing adulterations.

Under Section 403(g) a food is deemed to be misbranded,

> If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by Section 401,[28] unless (1) it conforms to such definition and standard. . . .[29]

The critical point, which the court must determine under Section 403(g), is whether the food in question *purports to be*, or whether it *is represented as* the food for which a standard has been prescribed. A finding that the food meets one of those alternative conditions is, therefore, a prime limitation upon the operation of the provision, and, if it is charged that the food is misbranded "when introduced into or while in interstate commerce," it must be shown that it "purports or is represented" at that time to be the standardized food.

It must also be remembered that the aim of Section 401 is to provide for a standard for a food "under its *common or usual name* so far as practicable." (Italics supplied.) The reach and effect of Section 403(g) may now be tested in the light of certain other sections

[28] See footnote 2.

[29] According to the regulation of the Federal Security Administrator, a food does not conform if it contains an ingredient not authorized by the standard, or fails to contain a required ingredient, or if it contains more or less of an ingredient than the quantity prescribed. 21 *Code of Federal Regulations*, Section 1.14.

of the statute, of several pertinent judicial pronouncements, of administrative practice, and of the legislative record.[30]

Judicial Decisions

The first critical examination of the question was in the *Farina* case.[31] This was an appeal, as authorized under Section 701(f) of the Act, from an order of the Administrator establishing definitions and standards of identity for "farina" and "enriched farina." [32] It brought a decision by the United States Supreme Court that a food which purports or is represented to be one for which a standard has been established, and which contains an ingredient not authorized by the standard, is misbranded under Section 401, in spite of the fact that its labeling is honest. It is useful to remember that this was the extent of the court's ruling. It was unnecessary to decide more than that.

Both the standard for "farina" and that for "enriched farina" were pertinent. The product was sold as "Quaker Farina Enriched by the Sunshine Vitamin." It failed to conform to the standard for "farina" by reason of its content of Vitamin D, which was not named by the standard either as a required or an optional ingredient. It did not conform to the standard for "enriched farina," since it did not contain the required vitamins B_1, riboflavin, niacin and iron.

It was the position of the government that the standard might properly limit the composition of the defined food to ingredients specified in the standard, "regardless of label disclosures and wholesomeness of proposed variants." [33] This principle was not specifically dealt with, however, in its relationship to the name under which the food was sold, since it was an assumption of the case that the food purported to be or was represented as the standardized article. The court's understanding of the underlying issues is revealed in the following quotation from the opinion:

> Respondent asserts, and the government agrees, that the act as supplemented by the Administrator's standards will prevent the marketing of its product *as*

[30] Such a test will also reflect to some degree the extent of authority which may justifiably be read into the general misbranding and adulteration provisions of the Act, which alone are applicable to unstandardized articles.

[31] *Quaker Oats Company v. Federal Security Administrator*, 318 U. S. 218 (1943).

[32] The standards are set forth at 21 *Code of Federal Regulations*, Sections 15.130 and 15.140.

[33] Brief for the Federal Security Administrator, p. 31.

"farina" . . . and that respondent cannot market its product *as* "enriched farina" . . . . (Italics supplied.)[34]

It was contended by respondent that this result was not contemplated by the statute and that the regulations prescribing the standards were unreasonable and were not supported by substantial evidence.

The court rejected these contentions and adopted the view that the purpose of the elaborate standard-making procedure established by the statute was to assure regularity and soundness of composition for products which might be accepted by the public as foods for which standards had been prescribed, if sold under the common or usual names of such foods. It said:

> As we have seen, the legislative history of the statute manifests the purpose of Congress to substitute, for informative labeling, standards of identity of a food, *sold under a common or usual name, so as to give to consumers who purchase it under that name* assurance that they will get what they may reasonably expect to receive.[35] (Italics supplied.)

The adoption of this view resulted in the destruction of an established product which, before the advent of the farina standard, had been an entirely proper and legitimate item for interstate marketing as "farina." The court did not, however, as the above quotations demonstrate, decide that such a product could not be sold if it were not characterized as "farina." [36]

The *Farina* result was taken as controlling by the Circuit Court of Appeals for the Second Circuit in the *"Tomato Catsup"* matter.[37] This food was sold as "Sanford Tomato Catsup with Preservative," with a statement upon the label that the product did not conform to the government standard for "catsup" [38] and contained one tenth of

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[34] 318 U. S. 224.

[35] 318 U. S. 232.

[36] This fact is probably of little practical consequence for the producer of a high-grade product who has established a market for it under the common name of the food for which the standard has been prescribed. The effect is to prescribe the sale of the food under that name. See *Houston v. St. Louis Independent Packing Co.*, 249 U. S. 479 (1919), where the court upheld a determination of the Secretary of Agriculture under the Meat Inspection Act (21 U. S. C., Section 71), that it would be deceptive to label as "sausage" an article containing more than two per cent cereal, even with qualifying words showing the presence of cereal in excess of two per cent. Whether a name is found to be "false or deceptive" within the meaning of the Meat Inspection Act or whether it is determined that a food is "represented as or purports to be" one for which a food standard has been prescribed, the result is the same where products are concerned which must, as a practical matter, be sold under a name known and accepted by the public. If, however, it is sound, the view expressed in the text of the effect of the *Farina* decision is of considerable significance where there is question of a new product which varies from the standard and has not become known to the public under the common name of the standardized food.

[37] *Libby, McNeill & Libby v. United States*, 148 F. (2d) 71 (CCA-2; 1945).

[38] 21 *Code of Federal Regulations*, Section 53.10.

one per cent benzoate of soda. Since the definition and standard of identity did not authorize the use of benzoate of soda in catsup, the article was seized for failure to conform in that respect.

The court, holding the food to be misbranded, said that,

> If producers of food products may, *by adding to the common name of any such product mere words of qualification or description,* escape the regulation of the Administrator, then the fixing of a standard for commonly known foods becomes utterly futile for the protection of the consuming public.[39] (Italics supplied.)

The opinion observed further that the character, appearance, and use of the product led to the conclusion that it purported to be catsup, and the opinion rejected the argument that " 'purport' is limited to what is disclosed by the label *and to that alone.*" [40] (Italics supplied.) It seems a fair inference that it was the combination of these factors *and* the labeling which led to the conclusion that the article "purported" to be catsup. In effect, this combination added up to a sale of the product *as the food for which the standard had been prescribed.*

Although the courts did not so decide, it may be said that, in a very real sense the products in both this and the *Farina* case were *represented* to be the standardized foods, within the meaning of Section 403(g). That section does not depend for its application upon a representation that the food alleged to be misbranded is farina or catsup *as described in the standard.* The government needed only to show that it was represented as a food falling within the usual concept of "farina" or "catsup," the foods *for which* the standards had been prescribed.

It seems possible to conclude that a food which does not conform to the pertinent standard is misbranded under Section 403(g), regardless of whether it is honestly labeled and its labeling declares the manner of departure from the standard, if, nevertheless, *it is sold as the food for which the standard has been prescribed.* It is reasonably evident that the articles involved in the *Farina* and *Tomato Catsup* cases were both sold and accepted by purchasers as "farina" and "tomato catsup." [41]

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[39] 148 F. (2d) 73.

[40] 148 F. (2d) 73.

[41] It should be noted, relative to the preceding discussion of unstandardized foods, that the *Farina* and *Tomato Catsup* cases seem to indicate that something was added by Section 403 (g) to the sanctions of the general adulteration provisions of the statute, since it seems hardly likely that either the "Quaker Farina" or the "Libby Catsup" would have been condemned by the courts before the promulgation of the two standards. Both foods had been established in the interstate market for substantial periods of time.

Two more recent decisions present another and strikingly different aspect of the same problem: the *Fountain Fruit* and *Grape Jam* cases.[42] They are pertinent to the questions: May a standardized food be imitated? Is a food subject to a charge of misbranding under Section 403(g) by reason of the fact that it is identical with the standardized article except for the omission of an ingredient provided for in the standard, or the substitution therefor of another ingredient, if the article is not sold as the standardized food?

In the first case, it was shown to the satisfaction of the district court that "Southland Peach Fountain Fruit," and certain companion products, were bought by merchants as fruit preserves, for which a definition and standard of identity had been prescribed,[43] and that they "purported" to be preserves within the meaning of Section 403(g), but did not conform to the standard. The conclusion seems sound under the test suggested in connection with the discussion of the *Farina* and *Tomato Catsup* cases.[44] The court, however, made this observation:

> This was, indeed, a new venture in trying out a table food, and had the claimant plainly labeled the food by true description, the label being in bold type, recommending it for use in place of preserves, jam, or jelly, there could have been no objection.[45]

The court did not take account, in the published opinion, of the concern of the Food and Drug Administration arising from the fact that a food which looks and tastes like the genuine article is inherently susceptible of being deceptively handled when served under circumstances where the label is not before the consumer and when the food is no longer in interstate commerce.

In the *Grape Jam* case, the government was denied condemnation of "Delicious Brand Imitation Grape Jam," and other flavors, which did not conform to the applicable standard for fruit preserves[46] by

[42] *United States v. 99 Cases . . . Peach Fountain Fruit, etc.*, (DC Tenn.; 1948) [CCH *Food Drug Cosmetic Law Reports* ¶ 7097]; *United States v. 62 Cases . . . Jam, etc.*, (DC N. Mex.; 1949) [CCH *Food Drug Cosmetic Law Reports* ¶ 7134].

[43] 21 *Code of Federal Regulations*, Section 29.

[44] The evidence that the fountain fruit was bought by merchants as preserves indicates that, unlike the poppy seeds and "Pop'n Oil," it was sold in interstate commerce as the standardized food.

[45] After this article was submitted for publication, information was received that, in an unpublished order, the quoted language was deleted from the memorandum opinion of the court in the *Fountain Fruit* case on the ground that it "might be misleading" and is of "no merit insofar as the decision of the controversy is concerned." Memorandum filed October 27, 1949.

[46] 21 *Code of Federal Regulations*, Section 29.

reason of a shortage of fruit, replaced by pectin. The government has appealed.

The libel in this case alleged that the article was misbranded under Section 403(g) when introduced into and while in interstate commerce and while being held for sale after interstate shipment. The court (Judge Hatch) pointed to the statutory provision that an "imitation" is misbranded *"unless* its label bears, in type of uniform size and prominence, the word 'imitation' and immediately thereafter the name of the food imitated" [47] (italics supplied), and regarded the quoted language as a Congressional sanction of imitations labeled as therein specified. Citizens should not, thought the court, "be subjected to the hazards of administrative or judicial interpretation, extending restrictions of the law far beyond the plain meaning of the language used." [48]

Judge Hatch might have added, in support of his position, that Congress knew how to ban imitations, as such, when its purpose was to do so, as the corresponding provision, Section 502(i)(2), relating to drugs, sufficiently demonstrates. That section simply, and plainly, declares a drug to be misbranded "if it is an imitation of another drug." There is no qualification or condition dependent upon manner of labeling.

The court assumed, without discussion in the published opinion, that the "grape jam" was an imitation, and its decision was predicated upon that assumption.[49]

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[47] Section 403 (c) of the Act.

[48] An expression of a doctrine which, perhaps, is renowned today, not so much for soundness of principle as for its failure to find frequent practical application.

[49] There was a substitution, pectin for fruit, which cheapened the food, and the "jam" would lend itself to deception if its labeling did not, in some manner, clearly reveal its "inferiority." As a matter of record, these two characteristics, substitution and susceptibility to passing off, have loomed large, both in the legislative history of the present statute and in litigation under the 1906 Act as tests for "imitations" in the statutory sense. Products with these characteristics were frequently attacked as imitations by the Food and Drug Administration in judicial proceedings. See, for example: *United States v. Ten Cases . . . Bred Spred,* 49 F. (2d) 87 (CCA-8; 1931); *United States v. 49½ Cases of Bred Spred,* (DC Mich.; 1927). Notices of Judgment under the Federal Food and Drugs Act (1906), No. 17351; White and Gates, *Decisions of Courts under the Federal Food and Drugs Act,* p. 1204; *United States v. Schider,* 246 U. S. 519 (1918), "Compound Ess Grape," containing no product of the grape; *Weeks v. United States,* 245 U. S. 618 (1918), "Special Lemon, etc.," represented to be lemon oil, but containing no such ingredient. Also: *United States v. Five Cases of Champagne,* 205 Fed. 817 (DC N. Y.; 1913); *Hudson Manufacturing Co. v. United States,* 192 Fed. 290 (CCA-5; 1912); *United States v. One Carload of Corno Horse and Mule Feed,* 188 Fed. 453 (1911). Further, in *Land O'Lakes Creameries, Inc. v. Paul V. McNutt, Federal Security Administrator, et al.,* 132 F. (2d) 653 (1943), it was the position of the government that what Section 403 (c) is directed at is preventing a

The case is important because it involves both the interrelation of Section 403(g) and other misbranding provisions of the Act and the scope of that section.

There can be no question that an article may be misbranded under two or more of the misbranding sections of the statute. In this sense Sections 403(c) and (g) are independent one of the other, and the fact that the "grape jam" bore the label "imitation" did not *necessarily* preclude the application to it of Sections 403(g). If, for example, the article were actually sold as the standardized food, Section 403(g) would be applicable under the test which has been advanced, just as, if its container were so filled as to be misleading, Section 403(d) [50] would apply.

Apparently, however, it is the government's view that the article was misbranded under Section 403(g) merely because it was an imitation of (or resembled) a standardized food, in the face of the apparent purpose of Section 403(c) to relieve imitations labeled as such from a charge of misbranding based, in effect, on the fact that they *are* imitations.[51] This simply means that no standardized food can legally be imitated. The underlying reasoning might logically be extended as well to unstandardized foods labeled as imitations if it could be shown, for instance, that cheaper ingredients had been substituted for those customarily used and understood by consumers to be constituents of the foods.

The court did not find that the "grape jam" was sold as the standardized food at the time it was introduced into or while it was in interstate commerce. But the government maintained, as it did in other cases which have been discussed, that it was misbranded at that time, without regard to its labeling. Here again, the implication is that any product which resembles an established food, whether it is a cheapened article or a more expensive one, will be in danger of attack as in violation of Section 403(g) or, if no standard

(Footnote 49 continued.)
spurious food being passed off as genuine, 132 F. (2d) 658; and that the determinative element in the question of the applicability of that section is the likelihood of deception resulting from the physical properties, labeling, or circumstances of sale of a product; that such is the purport of the legislative history of the section, and of the corresponding provision of the 1906 Food and Drugs Act (Section 8, First), as well as of long-standing administrative interpretations. (Brief of Respondent, p. 28, *et seq.*)

[50] Section 403 (d): A food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading.

[51] In the government's view it is apparently immaterial whether the food is an imitation in the statutory sense.

is involved, of the general adulteration sections of the statute.[52] Such an implication would not have arisen had the case been confined to the other allegation which was made: that the food was misbranded *while being held for sale* after shipment in interstate commerce.

We may suppose, for example, that the makers of "Quaker Farina" desired to mix with the product another cereal, in a proportion insufficient to materially change its physical appearance, but adequate to enhance its properties of flavor or nutrition, or adequate for some other reason to gain for it a greater public acceptance. Even if such an item were marketed under a fanciful or distinctive name unrelated to "farina," it would appear, under the interpretation of the law apparently underlying the institution of the proceedings which we have examined, that the new food would be regarded as misbranded or adulterated, or both, when shipped in interstate commerce.

It is quite certain that the mere use of a standardized article in or upon another food, as, for instance, jelly in cake, does not run athwart the law. Nor could a position be justified, in principle, that two foods cannot be combined, regardless of whether either or both are standardized articles. That the combination looks like, and may without its labeling be mistaken for, a food for which a standard has been prescribed, does not convincingly indicate a justification for a departure from that principle under the statute as it stands today. This observation seems equally applicable to the situation where the use or omission of a particular ingredient cheapens the entire product.

Identity

A critical factor in the problem of the effect of departures from a standard is the question of identity: the central consideration in

[52] The recent case of *United States v. 716 Cases . . . "Del Comida Brand Tomatoes . . .,"* (CA-10; 1950) [CCH *Food Drug Cosmetic Law Reports* ¶ 7143], is further suggestive of the trend of government policy. The food was condemned as adulterated under Section 402 (b) (2) in that a product containing water had been substituted wholly or in part for tomatoes, and as misbranded under Section 403 (g) (1) in that it failed to conform to the definition of standard of identity for canned tomatoes (21 *Code of Federal Regulations*, Section 53.40). The government appealed from an order of the lower court that the article be released to the claimant for the purpose of truthful labeling. The court of appeals reversed, holding that an article condemned as adulterated could not be cured of the adulteration by relabeling. The court's language is far from precise. Although it characterized as unnecessary a consideration of whether the article was misbranded under Section 403 (g), it stated, apparently in some confusion, that "the use of a substandard label does not raise the standard of identity to comply with the Act and regulations." In fact, no practical alternative to the sale of such a simple, natural food as canned tomatoes readily suggests itself. So marketed, it would be misbranded under Section 403 (g) because of failure to conform to the standard.

the standard-making procedure under Section 401. The standard establishes the identity of the article. Is this identity changed by the omission from the food of a substantial portion of the prime ingredient, as in the *Fountain Fruit* and *Grape Jam* cases? If so, it would seem that the products may properly be marketed if they are properly labeled.

In evaluating the question, we are entitled to place the theory of suppression indicated by the above-examined cases against the background of related official actions of the Food and Drug Administration and the Congress itself in dealing with standards of identity. In so doing, although we find that the problem is closely linked to the concept of identity, we fail to discern a consistency of treatment of like factual situations.

Cheese.—The definition and standard of identity for "cream cheese" and that for "neufchatel cheese" [53] differ only in that under the latter the product contains less milk fat and more moisture, not less than 20 per cent milk fat as against a requirement of at least 33 per cent for cream cheese.

"Foreign fat" coatings for chocolate products.—The standards for "sweet chocolate and vegetable fat (other than cacao fat) coating" and "sweet cocoa and vegetable fat (other than cacao fat) coating" [54] differ from those for other chocolate coatings, for example, sweet chocolate coating,[55] primarily in that a vegetable fat other than cacao fat may be added to the basic chocolate or cocoa ingredient to obtain the desired fat content of the food. In none of the several other standards for cacao products may a foreign fat be used.

Oleomargarine.—This product, long productive of political controversy and economic conflict between its manufacturers and producers of dairy products, was one of the first foods standardized under Section 401. It is a substitute for the natural food, butter, but was recognized by the Circuit Court of Appeals for the Eighth Circuit in the *Land O'Lakes* case [56] as having an identity of its own, a point of view necessarily inherent in the administrative decision to pre-

[53] 21 *Code of Federal Regulations*, Sections 19.515 and 19.520.

[54] 21 *Code of Federal Regulations*, Sections 14.11 and 14.12.

[55] 21 *Code of Federal Regulations*, Section 14.6.

[56] *Land O'Lakes Creameries, Inc. v. Paul V. McNutt, Federal Security Administrator, et al.*, 132 F. (2d) 653 (1943).

scribe a standard for the product. The standard authorizes the use of artificial flavoring and coloring, with appropriate label declaration of their presence.

Butter.—The Butter Act [57] defining butter and prescribing a standard for that food specifically authorizes the use of "additional coloring matter" without a requirement of label declaration of its presence.

No quarrel with these administrative and legislative regulations is reflected by their citation here. They serve, however, along with the cases which have been discussed, as illustrative examples of the difficulty of charting a course of consistency in the conceptual field of imitations and substitutions of food products or their ingredients without explicit statutory guidance. By the same token, they suggest that, in the language of Judge Hatch in the *Grape Jam* case, the "hazards of administrative or judicial interpretation" in that field are somewhat formidable.

Thus we see that neufchatel cheese, in which water replaces a portion of the milk fat used in cream cheese, enjoys an identity of its own and is officially standardized, while "imitation grape jam," in which pectin replaces the fruit used in the standard product, is proceeded against as misbranded. "Foreign fats" receive government blessing for addition to "chocolate" coatings in lieu of cacao fat, although the consuming citizenry are presumably ignorant of the "substitution."

Is there, in consequence of the fact that a cheapened food such as neufchatel cheese has acquired the dignity of government standardization, a greater assurance that it will be more honestly marketed than unstandardized foods labeled "imitation" or "substitute" or with some other equally revealing labeling? [58]

The government's argument that it was in the interest of the consumer to recognize the separate identity of oleomargarine and to establish a standard for that food was deemed sufficient by the circuit court of appeals in the ***Land O'Lakes*** case. There seems little likelihood, however, that consumer interest could have been shown had the protective devices not existed which were thrown about the

[57] 42 Stat. 1500, March 4, 1923.

[58] This query does not imply criticism of the concept that purchasers are benefited by the standard in so far as it stabilizes and insures the integrity of foods marketed under the names designated in the standard or otherwise sold as the product for which the concept that purchasers are benefited

marketing of that product by the Oleomargarine Tax Act [59] and the regulations promulgated thereunder. But it seems doubtful that the absence of such safeguards would justify the legal conclusion that the product did not possess a separate identity of its own, or that it could not be sold in interstate commerce as, for example, an imitation or substitute food, because of its inherent capacity for deception when served without the enlightening label, or because it resembled butter, a standardized food.

And finally, since some people prize yellowness in butter, we may ask whether they are the less deceived when, without label declaration, that quality is created or enhanced by the addition of color than if cherries, artificially colored red, were permitted to be used in canned fruit cocktail without informing the consumer of the presence of artificial coloring matter.[60]

If the seeming vagaries of legal theory above reflected are indicative, the manufacturer of a new product, cheap or dear, can have little of the consolation of certainty that he will not run athwart an application of the law which will condemn his product as contraband of commerce.

Conclusion

It is useful to recall again that Section 401 calls for the prescribing of a definition and standard of identity for a food "under its common or usual name so far as practicable"; and to bring forward the fact that the Senate Committee reporting on the proposal which eventually became Section 401 stated:

> It should be noted that the operation of the provision will in no way interfere with the marketing of any food which is wholesome but which does not meet the definition and standard, or for which no definition and standard has been provided; *but if an article is sold under a name for which a definition and standard has been provided, it must conform to the regulation. This does not preclude the use of distinctive individual brands.*[61] (Italics supplied.)

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[59] 53 Stat. 248, 26 U. S. C. 2300.

[60] The definition and standard of identity for canned fruit cocktail, 21 *Code of Federal Regulations*, Section 27.40, requires that the presence of artificial coloring be noted on the label of the food. The apparent inconsistency with the butter standard is not imputed to the Food and Drug Administration. The butter standard is a creature of Congress alone; see footnote 56. The comparison is made only as illustrative background for the viewpoint that the Food, Drug, and Cosmetic Act does not and was not intended to encompass all the disadvantages which may be visited upon consumers by the "unreconstructed fringe" of dishonest purveyors of foods or by legitimate business in foods which depart from official or customary standards.

[61] Senate Report No. 361, Seventy-fourth Congress, First Session. Dunn, C. W., *Federal Food, Drug, and Cosmetic Act* (1932), pp. 246-247. The "distinctive name proviso" of the Food and Drugs Act of 1906 and the unfortunate interpretation lent to it by some courts are discussed above.

This statement is entirely consistent with the decisions in the *Farina, Tomato Catsup, Fountain Fruit,* and *Grape Jam* cases, as well as with the suggestion herein made that a food is not misbranded under Section 403(g), if it is not sold *as* the food for which a standard has been prescribed. It is, however, not readily adjustible to the concepts underlying the government's position in the two proceedings last named, particularly with the background of other pertinent considerations which are above brought forward. Perhaps, therefore, the Senate Committee would regard the *Grape Jam* case, for instance, as an undue interference with a "food which is wholesome but which does not meet the definition and standard," yet is not "sold under a name for which a definition and standard has been provided."

It must be concluded that, in spite of the indicated limitations of jurisdiction, there is a clearly discernible administrative trend toward the barring from the channels of commerce of a wide segment of imitation and substitute foods, whether or not legal standards are thought to be applicable. The ultimate extent to which the policy will be pushed is not yet manifest. In spite of the dubious statutory basis for some of the judicial proceedings being instituted, prediction of outcome would be hazardous, against the background of the known propensities of courts in this field of the law. **[The End]**

Recall of Dangerous Drug—Oxylin Tablets

The Food and Drug Administration warns that a drug, Oxylin Tablets, is on the market which may cause poisoning. The tablets contain dangerous amounts of boric acid. After the product had been on the market for years, the formula was changed by adding the boric acid. Sensitive individuals may get enough boric acid from the uncoated Oxylin Tablets to result in serious poisoning. Available records show that the tablets have been distributed in Maryland, New Jersey, New York, and Pennsylvania, although the distributor does business as far west as Chicago (Federal Security Agency Release, May 11, 1950).

IMPORT CONTROL

Under Federal Laws

BY F. K. KILLINGSWORTH

THE PORTS OF THE NATION ARE THE GATES THROUGH WHICH COMES ADULTERATED FOOD —THE FDA HAS PROBLEMS AS GATEKEEPER

THE PURPOSE of this report is to bring up-to-date a previous article [1] on this subject. However, this note will cover only those changes effecting the Federal Food, Drug, and Cosmetic Act [2] and its enforcement. These changes will be reported in order of time rather than in order of importance or effect.

Seizure of Imports Under Act

The seizure power provided in Section 334 (a), Title 21, U. S. C. A., of the Act was held by the circuit court [3] to apply to an import shipment released on entry and admittedly adulterated at the time of entry.

Four shipments of fish from Canada were released upon entry by the Food and Drug Administration, and were delivered by the Bureau of Customs of the Treasury Department to the consignee at a warehouse in Detroit, Michigan. Later, it was discovered that the fish were infested with parasites, and seizure was effected under libels of information.

The appellant contended that:

(1) The shipments of fish from Canada to Detroit, Michigan, were (in foreign) not in "interstate commerce."

[1] 2 *Food Drug Cosmetic Law Quarterly* (1947) 498.

[2] 52 Stat. 1040, 21 U. S. C. 321, *et seq.*

[3] *230 Boxes, More or Less, of Fish et al. (J. Kozloff Fish Distributors, Claimant), Appellant v. The United States of America, Appellee* (CCA-6; 1948) [CCH *Food Drug Cosmetic Law Reports* ¶ 7089].

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(2) The fish were not adulterated in interstate commerce.

(3) Customs entry of the fish with the approval of the Food and Drug Administration did not make the shipment interstate commerce within the meaning of Section 334 (a), Title 21, U. S. C. A.

(4) The shipments, at the time of seizure, being still at the port of entry in the original containers, continued to be "imports" within the meaning of Section 381, Title 21, U. S. C. A.

The court said:

> The plain words of the statute reject the first contention of appellant. Section 201 (b) of the Act thus defines interstate commerce: "The term 'interstate commerce' means (1) commerce between any state or territory *and any place outside thereof*, and (2) commerce within the District of Columbia or within any other territory not organized with a legislative body." Section 321 (b), Title 21, U. S. C. A. (Italics supplied.)

and refused to restrict the definition to the traditional meaning of interstate commerce: commerce among the several states.

As to the appellant's second contention the court said:

> We need scarcely pause to comment that there is no merit in the second contention of appellant that the infested fish shipped from Winnipeg to Detroit were not adulterated in "interstate commerce," as alleged in the libels. Indisputably, the fish were adulterated by parasitic worm infestation when they were captured in the Canadian Lakes; they were so adulterated "when introduced into" interstate commerce; and were, of course, infested "while in interstate commerce." They were, therefore, within the plain coverage of the Act. *Seven Cases of Eckman's Alterative v United States of America*, 239 U. S. 510, 518.

The court then considered the last two contentions of the appellant together and held that the provisions of sub-chapter VIII, Imports

and Exports, Section 381, Title 21, U. S. C. A., were not "superior" to the first seven chapters of the Act in relation to imports and that the background of the Act of 1938 revealed in the Food and Drugs Act of 1906 [4] taken with the legislative history of the existing enactment did not support an inference that Congress intended to provide special preference for "citizen importers" and "foreign exporters" by excluding their commerce from the harshness of procedures provided against interstate commerce.

The court said:

> The reasonable interpretation would seem to be that Section 801 is designed to test the right to admission before an article may be brought into the United States; and that Section 334 (a) of Title 21, U. S. C. A., is operative after the article is released from the Customs and admitted into this country. *United States v. Nine Barrels of Olives,* 179 Fed. 983 (DC Pa., 1910).

and then quoted the Supreme Court as follows:

> The Supreme Court of the United States has said: "The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. *United States v. Dotterweich,* 320 U. S. 277, 280.

and continued:

> After an imported article has passed from the control of the Customs officials and has been released and delivered to the consignee, no authority under federal law or customs' regulations is found to authorize the Secretary of the Treasury to seize such imports except in cases where fraud was involved in their entry, as for instance in *Origet v. United States,* 125 U. S. 240; *United States v. One Diamond Ring,* 2 F. (2d) 732. The instant case involves no issue of fraud in the importation of the adulterated food articles. The Secretary of the Treasury and the Federal Security Administrator had completed the performance of the duties imposed upon them by Section 801 of the Act. When this point had been reached, the Food and Drug Administration took action by filing libels of information upon which the shipments of infested fish were seized where warehoused by the claimant. We conclude, as the district court did, that the articles of food so seized were subject to lawful condemnation in the manner pursued by due processes in conformity with the statute.

The court affirmed the decree of condemnation entered in the district court.

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[4] 34 Stat. 768 (1906), 21 U. S. C. 1.

The importance of this decision is evident. The protection of the public from unfit foods, drugs, and cosmetics, of whatever source, is paramount, and this decision has confirmed the position of the Food and Drug Administration that the public can be fully protected from adulterated or misbranded foods, drugs, and cosmetics of foreign origin. The entrance of adulterated shipments into the United States has come about in the following ways, and these illustrations point up clearly the necessity for seizure power over import shipments not within the custody of the Bureau of Customs.

(1) The Food and Drug Administration simply does not have sufficient personnel to give import shipments complete coverage. In fact, at times, only a relatively limited proportion of the total entries at some ports are examined. It is clear that under such circumstances the seizure remedy is vitally required.

(2) Import shipments may become adulterated or misbranded by spoilage, by deliberate manipulation, et cetera, after entry, and must therefore be removed from commerce.

(3) It has happened on frequent occasions in the past that shipments previously detained and required to be exported under Customs' supervision have been re-entered at another port. Seizure of such shipments under the Food, Drug, and Cosmetic Act provides an effective means of public protection in such cases. Since re-entry of inadmissible merchandise constitutes a "fraud entry" under customs law and regulations, such shipments can also be seized by customs.

(4) An initial sampling may not be truly representative of the entire lot or disclose its true condition. We have, in the past, discovered cases of facing and plugging of shipments after entry, as well as upon entry. Shipments have been packed in full cars with all unfit fish carefully placed in the center of the cars. In other cases, we have found individual boxes of fish containing good fish on top and bottom and infested fish in the middle. Since the fish is either iced or solidly frozen, sampling difficulties at points of entry, often a railroad yard late at night, are readily apparent. In a few cases, the substitution of an entire lot of fish being entered with a released lot has been attempted. Customs laws and regulations permit the release of perishable merchandise to the importer prior to formal entry and prior to inspection by Food and Drug officials, provided an acceptable re-

delivery bond is filed by the importer, 19 U. S. C. 1448 (b), Section 859, Customs Regulations. The time period may exceed 48 hours under a recent amendment to the regulation cited.

(5) In a few cases, importers have deliberately sold and distributed to consumers detained adulterated import shipments in defiance of the detention orders. In one case, payment in full of the bond penalties still left the importer a money profit illegally obtained. This importer was later prosecuted and fined. Seizure in such cases is the only means of protection of the public from the foods, drugs, and cosmetics themselves.

(6) At time of entry, the Food and Drug Administration may not have evidence to sustain a detention order and may therefore be forced to release an import shipment, since it is required to act within a reasonable time; in the case of imports, usually a very short period. It may be able later to devise a means of detection by developing a new chemical method and to obtain proof legally sufficient to sustain a seizure action.

The Food and Drug Administration does not propose to abandon the remedies provided for by Section 801 of the Act and will use the seizure provision, in the case of imports, only where needed for public protection.

Prosecution of Foreign Shipper

In the previous article,[5] we stated that the Food and Drug Administration was of the opinion that a foreign shipper could be criminally prosecuted for a deliberate violation of the Federal Food, Drug, and Cosmetic Act, and that the Administration had obtained a grand jury indictment against a foreign shipper because he shipped in interstate commerce from Montreal, Canada, through Rouses Point, New York, to Newark, New Jersey, food which had been previously entered at the Port of New York, denied entry, and subsequently exported to Canada. The case resulted in a plea of guilty, and on December 17, 1947, the defendant was fined $3,500.[6]

In this case, a shipment of frozen rock lobster tails from South Africa was denied entry at the Port of New York, because a material percentage of the tails was decomposed upon arrival. The shipment was subsequently exported to Canada under customs supervision. The

[5] 2 *Food Drug Cosmetic Law Quarterly* (1947) 525.

[6] N. J. 13288; F. N. J., F. D. C. 13201-13350, June 1949, p. 445.

Canadian buyer, on receipt of the goods, removed the legend "Produce of South Africa" from some of the boxes, repacked them in fish boxes labeled "Produce of Canada" (on some boxes the original markings were left intact), re-entered them at Rouses Point, New York, in four lots, invoiced as frozen lobster meat or as fresh lobster meat, and consigned them to a firm located in Newark, New Jersey. Subsequently, the New Jersey firm made several shipments to consignees in other states. Seven lots were seized and later destroyed by United States marshals,[7] and the New Jersey firm and three of its officers were also prosecuted[8] due to their complicity in the matter. A plea of guilty was entered on behalf of all of the defendants. The corporation was fined one hundred and fifty dollars, but sentence against the individual defendants was suspended.

The customs brokerage firm at Rouses Point which made the entries was not prosecuted. It made the entries in the regular course of its business; there was no evidence showing that it knew of the true nature of the rock lobster tails or of the plot to circumvent the law.

Appeal Procedure

In the previous article,[9] appeal procedure was discussed. Due to a reorganization within the Food and Drug Administration, the three regional offices were abolished. As a consequence the intermediate appeal step has been eliminated. A final order of a district chief is now appealable directly to the Commissioner of Food and Drugs and subsequently to the Federal Security Administrator.

Settlement of Claims for Liquidated Damages

On September 2, 1948, the joint regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act issued by the Secretary of the Treasury and by the Secretary of Agriculture (from which the Food and Drug Administration was transferred to the Federal Security Agency by Section 12 of Reorganization Plan No. IV, effective June 30, 1940), were amended[10] insofar as they applied to disposal in violation of the Act, regulations, or bond.

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[7] N. J. 11204, F. N. J., F. D. C. 11101-11300, May 1949, p. 244. N. J. 11400, N. J. 11401, F. N. J., F. D. C. 11301-11500, June 1948, p. 313 *et al.*

[8] N. J. 13629, F. N. J., F. D. C. 13501-13700, August 1949, p. 38.

[9] 2 *Food Drug Cosmetic Law Quarterly* (1947) 526.

[10] 13 *Federal Register* 5117, September 2, 1948.

This amendment vested in the local collectors of customs and chiefs of Food and Drug Administration districts, full authority to compromise claims for liquidated damages incurred by importers because of bond violations, if these officials are in full agreement. No appeal to the Bureau of Customs and/or to the Commissioner of Food and Drugs is provided. In case the local officials fail to agree on a proposed settlement of a claim for liquidated damages, settlement will be made by the Bureau of Customs and the Commissioner of Food and Drugs as heretofore.

This amendment has greatly facilitated the settlement of such claims, and has quickly resulted in the liquidation of a large backlog of cases arising during the war years.

Period of Import Status

On October 4, 1948, it was held by the Bureau of Customs and the Food and Drug Administration that import shipments held in bonded warehouses are in import status for the full three-year period allowed in the case of such entries, and that they are therefore subject to inspection and detention under Section 801, at any time during such period. Reconditioning, exportation, or destruction, and so on, are allowed under the same conditions as apply to import shipments detained immediately upon entry.

Amended Regulations

On November 6, 1948, the regulations (21 CFR, Cum. Supp. 2.114) exempting certain new drugs intended solely for investigational use from the provisions of Section 505 (a) of the Federal Food, Drug, and Cosmetic Act were amended.[11] The amendment applies to such drugs of foreign origin and sets forth full requirements for their entry into the United States.

On November 18, 1948, the regulations were amended[12] by a deletion of the requirement of the Shipper's Declaration on Form 197 or 198 Consular. It was felt by both the Bureau of Customs and the Food and Drug Administration that it no longer served any useful purpose.

[11] 13 *Federal Register* 6555-56, November 6, 1948.

[12] 13 *Federal Register* 6749, November 18, 1948.

Amendment of Act

On July 13, 1949, Section 502 (l) of the Federal Food, Drug, and Cosmetic Act was amended [13] to bring three new antibiotics, aureomycin, chloramphenicol, bacitracin, and drugs containing them or their derivatives under certification requirements. This section previously applied only to drugs consisting wholly or partly of any kind of penicillin or streptomycin and to drugs containing them or their derivatives.

This amended section applies to imports (as did the original section); foreign shipments of these drugs must have been compounded from certified batches to be admissible into the United States.

Conditional Entries

On October 18, 1949, Congress amended the Act by the enactment of Public Law 360,[14] Eighty-first Congress. The Act was signed by President Truman and became law on October 18, 1949.

This amendment gives Congressional sanction to the long standing practice of the Food and Drug Administration of permitting conditional entries; that is, allowing under its supervision, the reconditioning, relabeling, denaturing, or diversion to nonfood, drug, or cosmetic uses of detained import shipments. The amendment also provides for the assessment of expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) incurred by the government due to such supervision, on the importer, and provides, further, that in case of default by the importer or consignee of such payment the expenses shall constitute a lien against any future importations made by such owner or consignee.

On February 2, 1950, the regulations for enforcing Section 801 of the Act were amended [15] by the addition of a new section setting forth the costs chargeable in connection with relabeling and reconditioning inadmissible imports. These provisions are similar to those now in effect in cases of reconditioning and relabeling of seized merchandise under court supervision. **[The End]**

[13] Public Law 164, Chapter 305, Eighty-first Congress, First Session.

[14] Now generally known as the Crosser Act.

[15] 15 *Federal Register* 584, February 2, 1950.

The Practical Impact of the Proposed Uniform Commercial Code on Food Poisoning Cases

BY WILLIAM J. CONDON

THIS ARTICLE will consider the possible impact of the warranty sections of the proposed Uniform Commercial Code on the liability of the manufacturer or processor of food in food poisoning cases. We will consider the already powerful trend toward absolute liability of the manufacturer or processor in cases involving food products,[1] and the contribution or impetus which this Code can give to such a trend.

Preparation of Uniform Commercial Code

At the outset, a word about the Code is appropriate. Its preparation was a joint project of the American Law Institute and the National Conference of Commissioners on Uniform State Laws. The joint official comments of these two bodies, published with the draft of the Code, indicate that "the concept of the act is that 'commercial transactions' is a single subject of the law notwithstanding its many facets." The Code would replace the Uniform Negotiable Instruments Law, the Uniform Warehouse Receipts Act, the Uniform Sales Act, the Uniform Bills of Lading Act, the Uniform Stock Transfer Act, and the Uniform Trust Receipts Act, as well as regulate many aspects

[1] Mintener, "Food Products Liability Law," 1 *Food Drug Cosmetic Law Quarterly* (1946) 96; Mintener, "Food Products Liability Law," 2 *Food Drug Cosmetic Law Quarterly* (1947) 62.

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of commercial life not hitherto embraced by uniform legislation. In all, it is a monumental undertaking and represents years of the most careful research and painstaking labor.

We shall be chiefly concerned with the provisions of Article Two of the Code. This is a complete revision and modernization of the Uniform Sales Act. Incidentally, it might be pointed out here that the word "complete" in the preceding sentence is used advisedly and most appropriately. The draftsmen of this article have not seen fit to adopt verbatim any of the provisions of the present Uniform Sales Act. Their apparent purpose is to clarify existing ambiguities and to prevent confusion. The interesting question as to whether the rewriting of every section, whether presently ambiguous or not, is well adapted to the end sought must be left to another forum,[2] with the ultimate answer to be gleaned from future judicial history.

Position of Processor Under Present Law

In order properly to consider the effect the new Code will have, it is necessary first to have a picture of the position of the manufacturer or processor of food under the present law. The Uniform Sales Act sets out two implied warranties which apply to our type of case. These are the implied warranty of fitness for a particular purpose and the implied warranty of merchantability. They are provided for in subsections (1) and (2) of Section 15 of the Uniform Sales Act, which read as follows:

[2] Williston, "The Law of Sales in the Proposed Uniform Commercial Code," 63 *Harvard Law Review* (1950) 561. Professor Williston urges that at least the sales portion of the Code should not be enacted, *inter alia*, because of "the novelty of the phraseology and the iconoclastic provisions."

(1) Where the buyer, expressly or by implication makes known to the seller the particular purpose for which the goods are required, and it appears that the buyer relies on the seller's skill or judgment (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be reasonably fit for such purpose.

(2) Where the goods are bought by description from a seller who deals in goods of that description (whether he be the grower or manufacturer or not), there is an implied warranty that the goods shall be of merchantable quality.

You will note that the Sales Act refers to "buyer" and "seller." The ordinary sale made by a manufacturer or processor of food is made to a dealer for resale. Of course, if the dealer consumes the food and is injured or made ill thereby, he has his remedy in an action for breach of warranty against the manufacturer, his seller. But the normal case involves a purchase from the dealer. In such cases, it has generally been held that the injured person may not bring an action directly against the manufacturer or processor for breach of warranty.[3] This rule is based, not so much on the language of the Sales Act, as on the time-honored theory that a warranty attaches to a sale, is contractual in nature, and therefore only runs to one in privity of contract with the seller.[4] While the great weight of authority supports this doctrine,[5] there have been a number of courts which have permitted injured consumers of food to bring suit directly against the manufacturer. Many theories have been relied upon to support the results reached. For example, the warranty of wholesomeness runs with the product much as warranties of title run with the land;[6] the dealer assigns the warranty when he sells the product to the consumer;[7] the consumer is a third-party beneficiary of the warranty;[8] direct action against the manufacturer or processor of food is required by "social justice."[9] While the last-mentioned example contributes little to the purity of legal thought, it is commendable at least for its failure to torture existing doctrines or to indulge in mental calisthenics.

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[3] Williston, *Sales*, Section 244. Note 17 A. L. R. 672, 39 A. L. R. 992, 63 A. L. R. 340, 111 A. L. R. 1239, 140 A. L. R. 191.

[4] Jeanblanc, "Manufacturers' Liability to Persons Other Than Their Immediate Vendees," 24 *Virginia Law Review* (1937) 134.

[5] 17 A. L. R. 672, 39 A. L. R. 992, 63 A. L. R. 340, 111 A. L. R. 1239, 140 A. L. R. 191.

[6] *Mazzetti v. Armour & Company*, 75 Wash. 622 (1913).

[7] *Madouros v. Kansas City Coca-Cola Company*, 90 S. W. (2d) 445 (1936).

[8] *Ward Baking Company v. Trizzino*, 161 N. E. 557 (1928).

[9] *Catani v. Swift & Company*, 251 Pa. 52, 95 A. 931 (1915).

Progress Toward Absolute Liability

All of these cases illustrate the conscious efforts of courts to hold the manufacturer or processor liable to the injured consumer in the first instance. The first road used to reach this objective was the action in negligence.[10] Although this thoroughfare has been broadened considerably by means of extensions of the doctrines of *res ipsa loquitur*, presumptions, inferences, and negligence based on violations of statutes,[11] more and more plaintiffs' counsel and courts have been casting covetous eyes upon the broad highway of implied warranty. This because proof of due care, if credited, will defeat an action for negligence. Many trial courts and juries attach great weight to the proof of care adduced by food manufacturers. Few, if any, homemakers observe all of the many sanitary precautions which are routine in the plants of America's reputable food manufacturers and processors. When a defendant proves that he exercised the highest degree of care consistent with the generally accepted methods in the industry abreast of the latest technological advances, holding him liable in negligence poses a serious problem in judicial technique. But this problem disappears into thin air if the action can be founded in warranty. For the liability based on breach of implied warranty is liability without fault.[12] No amount of care will avail the defendant. The cause of action is established upon proof of the existence of the warranty and its breach. The end thus achieved represents the goal sought by many legal writers for a great number of years.

The chief draftsman of the Code, Professor Llewellyn, writing some twenty years ago, stated the objective thus:

> What is wanted is to protect the consumer dependent on a producer who is a stranger, or even anonymous. That needed protection is twofold: to shift the immediate incidence of the hazard of life in an industrial society away from the individual over to a group which can distribute the loss, and to place the loss where the most pressure will be exerted to keep down future losses . . . and it is desired to do this in the quickest, least expensive, most effective way. . . . Obviously, the place of primary incidence should, then, be the group which is in substantial control of the production. The first group liable, to any consumer, should be the manufacturer. . . . The consumer, barring his own fault in use,

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[10] 17 A. L. R. 672.

[11] 17 A. L. R. 672, 39 A. L. R. 992, 63 A. L. R. 340, 111 A. L. R. 1239, 140 A. L. R. 191.

[12] Prosser, "The Implied Warranty of Merchantable Quality," 27 *Minnesota Law Review* (1943) 117.

should have no negligence to prove. That the article was not up to its normal character should be enough.[13]

The author goes on to say:

> Under such an ideal system of law the loss would lie ultimately where it belongs, on the consumers of the article concerned en masse, in competition with other articles each carrying its own true costs in human life and effort.[14]

We shall see a little further on how well Professor Llewellyn has translated this aim into statutory language in the Code. It is to be noted that the quotation just read is not confined to food.

As far back as 1938, Professor Feezer[15] noted that food manufacturers were generally held liable for defective products without proof of any real negligence, and he urged at that time that this strict liability be extended to all manufacturers. This, he thought, should be done by the courts themselves. While he admits that it would be desirable if a symmetrical pattern of precedent could be followed in effectuating this policy so as to please the "conceptualists" in the profession, he nevertheless feels that if such harmony cannot be achieved, little harm will have been done because, after all, at least one lawyer disagrees with every decision.

Philosophy of Absolute Liability

In addition to the works already mentioned, legal literature is replete with articles, notes, and comments urging the application of the doctrine of absolute liability to manufacturers. The underlying philosophy behind all this literature seems to be one of spreading the risk. It is felt that the manufacturer is in the best position to distribute the loss over the public as a whole. The liability, it is said, should be on the one whom it will encourage to prevent the risk from arising. The manufacturer is in control of the production of the article and can do most to insure its being safe for consumer use. As our industrial economy progresses and the consumer becomes more and more dependent upon the manufacturer for the necessaries of life, the former becomes more and more helpless to protect himself against defective merchandise. Further, the loss to the consumer may be tragic; to the manufacturer it is but another item of cost to be passed along to his customers.

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[13] Llewellyn, *Cases and Materials on the Law of Sales*, Callaghan & Company, Chicago, 1930, p. 341.

[14] Llewellyn, *Cases and Materials on the Law of Sales*, p. 341.

[15] Feezer, "Manufacturer's Liability For Injuries Caused By His Products: Defective Automobiles," 37 *Michigan Law Review* (1938) 1.

Other reasons may be found which motivate writers to espouse the cause of absolute liability. One author [16] complains that, unless this doctrine be extended at least to cover packaged goods, an injured plaintiff will need a particularly astute lawyer to guide him to a recovery under present law. The same writer [17] then indicates what he considers would be the ideal disposition of product liability cases involving packaged foods as follows:

> There should be an attitude recognized by the courts which will induce the manufacturers of packaged foods to settle quickly rather than to wear out the injured consumer by a long and expensive court procedure. The manufacturer, on the other hand, even though we assume that the unwholesome production could not have been prevented, is in a much better position to stand the immediate loss. This immediate loss might be covered by insurance, the cost of which could be passed on to the general public, or the manufacturer could shift the risk directly to the general public in the form of higher priced commodities, so no particular injustice would be done.

The voices raised in support of the absolute liability doctrine are respected ones, and the arguments they advance present a tremendous emotional appeal. In our day, it is a courageous man indeed who will rise in opposition to any reform which would lift a burden from the individual and place it on the broader shoulders of "the public," or "the wealthy," or "business." Nevertheless, however humbly the task be undertaken, it is essential for a proper appraisal of the subject of our discussion that we point out what appear to us to be weaknesses in these arguments.

Burden of Loss on Manufacturer

It sounds very impressive to say that the manufacturer can distribute the loss to the public as a whole. Any businessman could testify that it isn't as easy as it sounds. These losses cannot be depended upon to fall, like a sales tax, in direct proportion to a manufacturer's volume of sales. In this connection, it is well to bear in mind that ours is still a competitive economy. One with particularly heavy losses in any given period cannot pass them on to his customers and remain in competition with his more fortunate brethren.

It is true that the possibility of incurring losses spurs manufacturers to greater effort to prevent the risk from arising. However,

[16] Jeanblanc, "Manufacturers' Liability to Persons Other Than Their Immediate Vendees," 24 *Virginia Law Review* (1937) 134.

[17] Jeanblanc, "Manufacturers' Liability to Persons Other Than Their Immediate Vendees," 24 *Virginia Law Review* (1937) 134.

it is submitted that no need has been demonstrated commensurate with the drastic burden sought to be imposed. Certainly, with regard to the food industry, one need only to read the provisions of the Federal Food, Drug, and Cosmetic Act [18] and the cases decided thereunder to find ample reason for food manufacturers and processors to use the utmost care in the handling of their products. Furthermore, we will show that in the case of food poisoning the care used by the manufacturer is not a guarantee of wholesomeness to the consumer even though the product be completely pure when it leaves the manufacturer's plant.

The argument that the manufacturer is better able to bear the loss than the consumer, while stating an economic truism, also sets out a startling norm for determining legal rights and liabilities. Someone has said, "A very bad man may have a very good case." A corollary could be that a very wealthy man may have a meritorious defense, and liability should be predicated on something more than the disparity in the relative financial condition of the parties. While it may land us in the category of "conceptualist" we believe that principles of law and the administration of justice should be made of sounder stuff.

Implicit in the argument that the manufacturer is better able to bear the loss than the consumer is the thought that the manufacturer can also better bear the loss than the retailer. This is necessarily so, because, with very limited exceptions,[19] the consumer has a perfectly good remedy in warranty against his immediate vendor, as well as an action in negligence against the manufacturer.

Use of Warranty Remedy Against Retailer

An objection to the use of the warranty remedy against the retailer has been that a system dependent upon a series of recoveries over is circuitous and wasteful.[20] Further, it is said that financial irresponsibility at any point along the line will defeat it.[21] It is, therefore, now

[18] 21 U. S. C. 301. The Federal statute is cited because it is the most widely known and because the great bulk of the food manufactured commercially in the United States is subject to its provisions. However, the same principle and argument applies to the statutes governing food manufacturers in the various states. The effectiveness of the state statutes is subject to considerable variance depending upon the character of their enforcement.

[19] *Scruggins v. Jones*, 207 Ky. 636, 269 S. W. 743 (1925); *Pennington v. Cranberry Fuel Company*, 117 W. Va. 680, 186 S. E. 610 (1936).

[20] 42 *Harvard Law Review* (1928) 414.

[21] 42 *Harvard Law Review* (1928) 414.

sought to relieve all parties standing in a position intermediate to the manufacturer and the consumer of all responsibility on the amazing ground that they might not be able to pay the judgment!

Apparently no thought is given to the possibility that the responsibility might properly belong to one of these parties. Where would that leave our manufacturer? Would he be permitted to show an intervening cause? If so, how hopeful could he be that a jury would send the plaintiff off to seek his remedy against the proper person? If a judgment were rendered against a manufacturer in such a situation, what remedy would he have against the true wrongdoer? If, as we believe, he would have no remedy, then indeed would the manufacturer be an insurer of his product all the way to the consumer's stomach! We can find no justification in fact or in theory for the imposition of such a burden.

At this point the oft-quoted language of Judge Augustus Hand in the case of *Valerie v. Pullman Company* is appropriate:

> My own feeling is that protection to the public lies not so much in extending the absolute liability of individuals, as in regulating lines of business in which the public has a particular interest in such a way as reasonably to assure its safety. In other words, pure food law, and rigorous inspection of meats, canning factories, and other sources of food supply, would seem to me a much more effective way of protecting the public than by the imposition of the liability of an insurer upon those who furnish food. The former method corrects the evil at its source. The latter method only imposes an obligation in cases which *ex hypothesi* cannot be guarded against by the individual by the exercise of due care. It shifts the loss from the person immediately suffering the injury to a person who has neglected no precaution in supplying the food. This certainly is not in accord with the general tendencies of the comon law. I am inclined to think that the imposition of such an obligation would tend to lead in the long run to the prosecution of unfounded claims, rather than to the protection of individuals or the public.[22]

This dictum of Judge Hand has been characterized as fallacious [23] on the grounds that the two modes of protecting the public are not necessarily inconsistent and that the imposition of an "insurer's liability" does tend to correct the evil at its source. Without suggesting that the eminent jurist needs any defense or insinuating that we have any standing as his defender, it seems perfectly plain that Judge Hand was not guilty of either of the lapses charged. His whole point was that proper regulation was to be desired over absolute liability, and

[22] *Valerie v. Pullman Company*, 218 Fed. 519, 521.

[23] Perkins, "Unwholesome Food as a Source of Liability," 5 *Iowa Law Bulletin* (1919) 6, 86.

that if the former were achieved, the latter would be unnecessary. He perceived the dangers inherent in the absolute-liability rule as far outweighing its advantages so long as there was available another effective method of protecting the public. It is submitted that the public today is the beneficiary of far greater protection through regulation of the food industry than was the case when the *Valerie* decision was written.

This, then, is the present state of food products liability law and the general legal atmosphere into which the Uniform Commercial Code is to be introduced. It is appropriate now to inquire into its provisions. As might be expected, these provisions are intended to put in place the final peg in the change over from defendant's law to plaintiff's law. They would relieve courts from legal legerdemain and make absolute liability a reality.

Uniform Commercial Code

The sections of the Code with which we are concerned are three. For purposes of clarity we will set them out *in toto*. Section 2-318 provides:

Third Party Beneficiaries of Warranties Express or Implied

A warranty whether express or implied extends to any natural person who is in the family or household of the buyer or who is his guest or one whose relationship to him is such as to make it reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this section.

Section 2-718. Impleader by Buyer; Notice to Defend

(1) Where a buyer resells and is sued for any breach with regard to which he would have an action over against his seller he may

(a) implead his seller in like manner and with like effect as is or may be provided in the Federal Rules of Civil procedure; or

(b) give reasonable notice to his seller to come in and defend the action.

(2) Failure of a seller to defend after receiving such notice renders any adverse judgment in the action conclusive against him and makes him liable for all costs of the action including reasonable attorney's fees.

Section 2-719. Direct Action Against Prior Seller

Damages for breach of a warranty sustained by the buyer or by any beneficiary to whom the warranty extends (Section 2-318) may be recovered in a direct action against the seller or any persons subject to impleader under the preceding section. An action against one warrantor does not of itself bar action against another.

The official comment to Section 2-318 reads, in part, as follows:

Purposes:

This section, following the dominant trend of judicial opinion developed in the light of modern distribution methods and the fact of group consumption, is intended to broaden the right and the remedy of the consumer in warranty, to free them from any technical rules as to "privity" and to make them, insofar as feasible, directly enforceable against the party ultimately responsible for any injury. It seeks to accomplish this purpose without any derogation of any right or remedy resting on negligence. It rests primarily upon the merchant-seller's warranty under this article that the goods sold are merchantable and fit for the ordinary purposes for which such goods are used rather than upon the warranty of fitness for a particular purpose. In this respect, the warranty of merchantability does not depend on whether it is the buyer or the seller who selects the goods as does the warranty of fitness for a particular purpose.

Thus would Professor Llewellyn make his objective a reality through the medium of legislative enactment. These sections just quoted impose an absolute liability on manufacturers for defects encountered in their products by practically anyone in the world. They render the manufacturer liable to the consumer in the first instance in all cases except where the consumer chooses to pursue his remedy elsewhere.

Responsibility of Food Manufacturer

Applying these provisions to the food industry, it is submitted that the food manufacturer's warranty may run to anyone who consumes his product except a thief. He will, in effect, be an insurer of the wholesomeness of his product long after it has passed out of his control and after it may have passed through any number of hands. A consideration of the causes of food poisoning and the care required to avoid their incidence will, we think, demonstrate the unfairness of imposing an insurer's liability on the food manufacturer or processor in this type of case. For he may be held responsible for illness resulting from the consumption of his product even though that product was perfectly wholesome when it left his control.

The term "food poisoning" is used here in its scientific connotation; that is, poisoning of bacterial origin. We are not concerned with the deliberate addition of poison to food, nor with food allergies.

"Ptomaine Poisoning"

All of us have heard, from time to time, of someone's getting "ptomaine poisoning" from eating contaminated food. We shall let

the eminent Doctor Jensen, whose recently published book has provided the source for our bacteriological information, dispose of this old "chestnut." He says:

> At this time, we wish to stress the spurious basis for the concept of "ptomaine poisoning." The American Medical Association does not recognize this diagnosis as a clinical entity, and there is no foundation whatsoever for believing ptomaines to be poisonous. Until recently, purified ptomaines had never been fed to man as such. However, for ages the richest source of ptomaines known has been consumed by man in the form of limburger cheese. The "ptomaine poisoning" entity is no longer tenable. Ptomaines develop only during putrefaction of proteins. Anyone eating a putrefied food is negligent in a legal sense.[24]

Food Poisoning Bacteria

Of all the bacteria known to science, only four enter into the bacterial food poisoning picture. These are (1) Staphylococci, (2) Streptococci, (3) *Salmonella,* and (4) *Clostridium Botulinum,*[25] and the toxin-forming varieties of the first-named, Staphylococci, account for over 90 per cent of the unquestioned outbreaks of food poisoning in this country. Though the staphylococci can be found almost anywhere, the most likely sources of them are the nose and throat, boils, sores, and open cuts on fingers and arms. They form their toxins when they grow rapidly. It has been determined that in five to eight hours at temperatures between 60° F. and 115° F. they can form enough gastrointestinal irritants to produce their characteristic symptoms in man.[26] It might be pointed out here that, while the condition so adduced is not of itself fatal, the experience is not one which the sufferer would wish soon to repeat. As Dr. Jensen puts it:[27]

> Those who have volunteered to swallow the toxin can speak with authority, but meekly, on the loss of man's natural dignity for a few hours. After about two and a half hours, vomiting and diarrhea come on with a suddenness which leaves practically no time for reaching headquarters.

The streptococci produce much the same symptoms in man as the staphylococci except that the incubation period in the body is from ten to twelve hours. However, unlike the staphylococci, they do not form a toxin, but attack the small bowel directly. There are only four or five outbreaks on record where these bacteria were suspected.[28]

The *Salmonella* produces a gastrointestinal upset similar to that caused by staphylococci, but the infection is usually accompanied by

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[24] Jensen, *Meat and Meat Foods,* The Ronald Press Company, New York, 1949, p. 159.
[25] Jensen: *Meat and Meat Foods,* p. 159.
[26] Jensen, *Meat and Meat Foods,* p. 159.
[27] Jensen, *Meat and Meat Foods,* p. 160.
[28] Jensen, *Meat and Meat Foods,* pp. 160, 161.

a temperature. The *Salmonella* do not form toxins, and the incubation period in the body ranges from 12 to 72 hours. They grow at 60° F. to 105° F. and are killed at pasteurizing temperatures.[29]

The last of the four are the botulism bacteria, called *Clostridium Botulinum*. These spore-bearing rods will not grow in the presence of air. Hence, their greatest importance is in the field of canned foods. The toxins formed are neurotoxins which produce paralysis of the central nervous system. There is no known cure and the mortality is very high. Fortunately, the toxin is very easily destroyed by cooking for from 30 seconds to five minutes at 176° F., and the disease, known as botulism, is very rare. As has been said:

> Foods infected with *Clostridium Botulinum* usually putrefy with an indescribable cheesy stench, so that foods, especially meat products, infected with this organism would not be edible.[30]

From all of this it can be seen that all save the rarest of food poisoning sufferers owe their discomfort to the machinations of our little friends, the staphylococci. This fact justifies our taking a closer look at the facts indicated above concerning these genera of bacteria with a view to applying these facts to the problem which we have under discussion.

Staphylococci

First, it will be noted that the staphylococci are not toxic if only the cells themselves are ingested. It is only where these bacteria are permitted to grow rapidly outside the body that they form a toxin. Hence, the mere presence of staphylococci is not in itself harmful. Indeed, food infected with these bacteria is perfectly wholesome and will remain wholesome as long as it is properly handled.

In this connection, we should bear in mind that the most prolific sources of staphylococci are the nose and throat, boils, sores, and open cuts on the fingers and arms, and that these bacteria are airborne. Food, therefore, is subject to infection at any stage prior to consumption by exposure to air or to a person who coughs or sneezes a lot or who is afflicted with *any* of the other ailments mentioned. Hence, we may expect a regular presence of staphylococci on foods exposed to air and people, which cannot be prevented by any amount of precaution. It is important to keep constantly before us the fact that no fault

[29] Jensen, *Meat and Meat Foods*, pp. 161, 162. [30] Jensen, *Meat and Meat Foods*, p. 162.

attaches to the mere *presence* of these bacteria. It is the mishandling which permits the bacteria to grow and to produce their poison which constitutes the true cause of food poisoning.

Lastly, consider that the incubation danger zone lies between 60° F. and 115° F., and that, in a period of from four to eight hours in this temperature range, staphylococci can produce enough of their so-called "enterotoxin" to render a human being quite ill. In other words, these bacteria grow rapidly and produce their toxin quite efficiently at *normal room temperatures.* So that, in the relatively short space of five or six hours, perfectly wholesome and harmless food may be rendered poisonous by the simple expedient of leaving it out of the refrigerator. How often we all have seen meats and other foods left out of the refrigerator all day or over night? Nor must we be misled into believing we are safe because the foods left out were first cooked. While it is true that normal cooking will kill these bacteria, there is nothing in the cooking which will prevent a re-infection. Indeed, it has been said that "Cooked tissues appear to be more vulnerable to microbial action than raw tissues when kept under identical conditions." [31]

Unfairness of Strict Liability

It should not be difficult to perceive the problem which will face the manufacturer or processor of food when a rule of strict liability is imposed upon him. His will be a stricter liability than any heretofore known to the law. It will not be limited to cases where the poisoned food will have been started in motion by the manufacturer without technically provable legal fault. In practical effect, the warranty sections of the Code will render the manufacturer liable merely because he started on its way perfectly wholesome food which became contaminated with food poisoning through the neglect of some other person after the food was out of the manufacturer's control. In short, the manufacturer or processor of food will be held as an insurer that his product will still be wholesome when consumed even though it may have been handled by dozens of persons after leaving his control. Indeed, he may conceivably be held as an insurer of all foods which accompany his product to the consumer's table.

This latter statement is not so far-fetched as it may sound. Rarely do people eat one food alone. Virtually all meals are a combination

[31] Jensen, *Meat and Meat Foods*, p. 168.

of foods. Let us conjure up a situation which is not at all unusual. At a typical mid-week meal the family consumes practically everything that was cooked, the dog gets the scraps, and after the dishes are done, no evidence of the dinner remains. Within a few hours everyone in the family shows unmistakable signs that all is not well. The family doctor makes a positive diagnosis of food poisoning. How does our family determine what food was at fault? It presents quite a problem, but is usually solved by someone's remembering that the meat had a slightly different look, or that the mayonnaise had a slightly different flavor, or that the canned tomatoes had a slightly different aroma. All the time, of course, the real culprit may well have been mother's custard pie which had stood on the shelf in the kitchen since morning. Now, if the meat packer may be sued directly for breach of warranty and every member of the family testifies as to the strange color of the meat, what can a jury be expected to do? The fact that there is no necessary relation between the organoleptic condition of a food and the presence or absence therein of food-poisoning bacteria will be of small comfort to the packer in such a case.

This is a prime example of the unfair and oppressive burden which a rule of strict liability would place on the food manufacturer. And this is not an unusual type of case; it happens regularly. Under the present state of the law the manufacturer has an excellent chance of successfully defending himself in such a situation. But it would require the highest optimism to predict similar success under a statute dedicated to the principle of placing liability on the one best able to bear the loss.

Nor does the oppressive and unfair burden of such a rule apply only to the case where a manufacturer's product is mistakenly accused of causing the illness. Suppose we change the facts in our example and assume that laboratory analysis of a sample of the meat proved beyond doubt that it was the vehicle which carried the enterotoxin which in turn made this family ill. Could the packers of this meat then expect to defeat an action in breach of warranty under the Code? Certainly, if the odds were against him in the previous example where there was no direct proof that his product was infected, of necessity they would be greater where his product was actually shown to be unwholesome when consumed. Yet, consider the possibilities.

This meat could well have left the packing plant without a single toxic staphylococcus on it. It could have become infected with the

bacteria at any point along its journey. Handling by persons with boils, sores, or cuts could be the source of infection. It could even pick up the bacteria from the air as it lay in the retailer's meat case as the result of a cough or a sneeze a dozen feet away. Finally the source of infection may be in the very home of the consumer. As we have seen, after infection it is necessary that these bacteria be exposed to temperatures between 60° F. and 115° F. for a few hours in order to produce their poison. This exposure, which constitutes the *real* fault, can also take place at any stage of this meat's journey through the market place. Obviously, it could happen in the consumer's home, and very often it does. For example, many housewives make a practice of stuffing a turkey the night before they plan to cook it. Not infrequently, it won't fit in the refrigerator, so it is left out overnight. The stuffing, of course, is an excellent culture medium for the bacteria, so if a few of them are present, the stage is set for a disastrous holiday. Another example is the salad which is prepared in the morning and kept in the pantry to be eaten at a buffet supper. No doubt all of us can think of cases of improper exposure of foods right in our own homes.

Although for convenience in discussion of our two hypothetical cases we have taken meat as the product involved and the meat packer as the defendant, it should be understood that the whole gamut of food manufacturers and processors are subject to the same conditions and liabilities. The food involved could just as well have been pastry, or cheese, or mayonnaise, or a whole host of other products.

Consumer's Action in Warranty

Under the present law, the consumer's action in warranty would be against the retailer. Except where one of the large chains is involved, the parties come into court on a relatively even footing. The "big corporation" atmosphere is lacking. Then, in our "wasteful and circuitous" system of actions over, each link in the chain of distribution comes into court and has the burden of establishing his freedom from fault. While there can be no guarantee that this system will disclose the wrongdoer in every instance, there is at least a chance to discover where the lapse occurred. How can this information be brought before the court under the Code where the manufacturer is sued directly in the first instance? Certainly the wrongdoer will not volunteer such testimony because, under Section 2-719, he himself will still be liable to suit by the consumer. Nor can the manufacturer bring the wrong

doer in as a party defendant because, under Section 2-718, the right of impleader runs only to the benefit of a buyer as against a seller. Furthermore, there is no duty running from a buyer to a seller properly to handle the seller's product. Hence, the manufacturer must fight it out alone and depend entirely upon his ability to convince the court that the product was free from contamination when it left his plant.

Obviously, in such a situation one of two things must happen. Either the manufacturer must be held liable, which on the facts would be a rank injustice; or the plaintiff must be sent out to start over against the retailer, or the true wrongdoer if he can find him. It is submitted that if the latter alternative is chosen the Code will have succeeded in defeating its own purpose. For, instead of relieving the plaintiff of the burden of involved and costly litigation, it will have doubled that burden.

It is submitted that, if courts and juries catch the spirit of the Code, the philosophy upon which the doctrine of absolute liability is based, there can be no doubt but what plaintiff will recover in such cases.

Wherein lies the justification for a result which seems to run counter to principles heretofore considered sacred by the law? Is it to be found in the desire to give the manufacturer greater incentive to keep his products free from defects? This can hardly be the answer when no amount of care and no amount of diligence, however great, on the part of a food manufacturer will insure the continued wholesomeness of his product after it has left his control. The only thing the manufacturer or processor of fresh foods could do to minimize the risk of such losses would be to eliminate the use of middlemen entirely and deal directly with the consumer. Obviously, conditions of modern life make this impracticable.

It is often said in justification of such a rule that the imposition of a rule of strict liability upon the manufacturer places the loss in the hands of him who is in the best position to distribute it among the public as a whole. We have already suggested that the validity of this argument is more apparent than real. In the complicated economic world of today it is unrealistic to think that every loss can be reflected in the price of the product. As Dean Roscoe Pound says, "There is very little if any validity in the proposition that compensation for loss and injury without fault of the utility or enterprise is passed on to the public."[32]

[32] Pound, "Newer Ideas of Liability," New York County Lawyers Association, Charles Evans Hughes Memorial Lecture, 123 N. Y. L. J. 523, 524 (1950).

Strict Liability as "Paternalism"

The real basis for the strict liability rule in these cases is found in its underlying philosophy, which might be labeled "paternalism." It seeks to remove the incidence of the hazard of life from the individual. Idealistically, it would place this hazard on the public at large; but failing this, its purpose is served by imposing a vicarious liability on someone who will be financially able to save the individual consumer harmless. And we have seen that, in practice, this may well include protecting the individual consumer against losses resulting directly from his own fault.

There are several objections to this philosophy as it is implemented and effectuated by the Code, and, more particularly, as it relates to the manufacturer or processor of foods. In the first place, the cost will not be passed on to the public. Even if it were so passed on, there is something wrong with a system which would convert every gastro-intestinal upset into a judgment which would be reflected in the food bill of every consumer. In the nature of things, this will include upsets caused by nerves, tension, allergies, and so on, as well as the relatively few that are properly ascribed to food poisoning. It will also embrace nausea and diarrhea which existed solely in the fertile imagination and scheming mind of the plaintiff. Coping with spurious claims is a serious problem to the food industry today; under the Code, it could present an intolerable burden.

Objection to Paternalistic Philosophy

The most fundamental objection to this paternalistic philosophy as applied through the medium of absolute liability of manufacturers is the fact that it is not founded on a sound moral basis. The ancient practice of robbing Peter to pay Paul stands on no firmer ground today than it ever did. Yet, this is precisely the principle sought to be invoked. The manufacturer, though completely without fault, will be required to assume the consumer's loss solely because he is presumed to be in a better financial position than the consumer to do so. The majesty of the law must necessarily be weakened by the adoption of principles inconsistent with good morals. And despite suggestions of eminent jurists to the contrary, moral values are constant and are not subject to change with the political temper of the people. It is axiomatic that if the principle is invalid, its application cannot be justified.

Dangers in Absolute Liability

A brief recapitulation shows that there is a growing tendency in the courts to hold manufacturers of food liable to consumers. The warranty sections of the Code will make this liability absolute. With respect to food poisoning of bacterial origin, we have seen that in cases of this sort the burden thus imposed on the manufacturer or processor is unjust, unwarranted, and oppressive. Because of the nature and causes of bacterial food poisoning, the rule of strict liability makes him an insurer of the wholesomeness of his product up to the very moment of consumption. Thus, he is left with no means of protecting himself against losses of this type, since he cannot control the handling of the product after it leaves his hands. There is also a very real danger that over the course of time the consumer's easy remedy against the manufacturer will actually promote carelessness and improper handling on the part of the middlemen and retail dealers; for, apart from the larger cities, the fear of liability to his customers is the only effective deterrent to insanitation that the average intrastate food merchant knows. Furthermore, there will be created a fertile field for the operations of the unscrupulous, and spurious claims will have opportunity to flourish as never before. What is already a vexing nuisance to manufacturers may become a problem of the first magnitude.

And all of this tremendous movement to relieve the plaintiff of his burden of proof, which finds its culmination in the provisions of the Code, has for its object to shift the risk of life from the injured individual to the most convenient victim. The manufacturer is seized upon as the victim because of his relative financial ability. There is thus evolved an insurance concept of liability which is unwarranted in fact and unsound in principle.

Before concluding, we wish to make it clear that we have no quarrel with the idea of relieving the citizen of a part of the tremendous burden he bears today. Our objections are addressed to the method proposed to effectuate this end. We believe with Dean Pound, that,

> There ought to be a better method of making the legal order effective to our humanitarian ideals than that of Robin Hood or that of the pickpocket who went to the charity sermon and was so moved by the preacher's eloquence that he picked the pockets of everyone in reach and put the contents in the plate.[33]

[The End]

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[33] Pound, "Newer Ideas of Liability," 123 N. Y. L. J. 524 (1950).

Rodent and Insect Infestation in Wheat and Flour

BY J. O. CLARKE

GOVERNMENT AND INDUSTRY ARE WORKING TO PERFECT BETTER MILLING PRACTICES

FOR THE PAST SEVERAL YEARS the Food and Drug Administration has been engaged in a program of factory inspections of flour mills. This work has been carried out as a part of a general program on sanitation of foods as authorized and directed by the Federal Food, Drug, and Cosmetic Act. One of the provisions of that Act requires food shipped in interstate commerce to be clean, and to be manufactured and held under sanitary conditions. We know that it is not possible for the flour industry consistently to produce flour which is absolutely free of inconsequential amounts of foreign material. In applying this section of the Act, the Food and Drug Administration is dedicated to the application of the rule of reason. In the milling industry, rodent and insect infestation are the most important elements contributing to insanitary conditions.

Many mills have been inspected under this program, and some have been found to be badly infested with insects or rodents. Appropriate legal actions have been taken. The milling industry recognized the conditions which existed in some mills and great progress has been made in correcting insanitary conditions. The Millers National Federation has been working on a self-improvement program for a number of years. Many individual mill companies have employed skilled per-

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sonnel to establish and maintain strictly sanitary conditions in their mills. As a result of the efforts of the industry, gross mill infestation is now being encountered less and less frequently by our inspectors. I think the milling industry should be commended for the progress already made, and I think that it has demonstrated that progress in this direction will continue.

Insect and rodent infestation in flour may originate in the wheat from which the flour is produced or may originate in the mill itself. Since the latter source of contamination has been materially reduced and since progress in this direction is continuing at an acceierated rate, we are now faced with a need for dealing with the matter of infestation in wheat itself.

Investigation of Infestation

Last fall discussions were initiated among the Food and Drug Administration, the United States Department of Agriculture, the flour milling industry, and the wheat producing industry which led to the development of an investigational program to determine the facts in regard to the infestation of wheat, and the degree to which the infestation can be prevented or removed by proper handling, storage, and milling practices. A similar program is under way in the corn meal industry.

The broad purpose of the program is to determine the level of internal and other insect and rodent infestation, and to determine the degree to which such infestation can be removed by good milling practices. It is also hoped to establish an adequate field test by means of which internal infestation can be detected. The results of the investi-

gation will be used by the Food and Drug Administration as a guide in planning future regulatory activities. The results may be valuable to those educational and governmental institutions interested in research work on grain and flour. The results may be used by the grain and flour industries in planning their own self-improvement programs.

There is a stern necessity for improvement in the wheat producing industry. In the production and marketing of many agricultural commodities there is an opportunity for the first processer to pick and choose raw materials of better quality for the production of food since there are industrial outlets which can take the less desirable raw materials. This is not normally true in the flour milling industry for the reason that our nation's food supply is so geared that a very large proportion of available wheat must go into human food. In these circumstances we cannot escape the conclusion that wheat from a long range standpoint must be protected from contamination and its fitness maintained for food purposes.

Types of Infestation

Like many crude agricultural products, wheat is subject to insect and rodent attacks from the time it is produced on the farm until it is converted into flour. Incidentally, the attacks of these pests may continue even after the flour is milled and until it is actually consumed as bread or other wheat products.

Rodent infestation is usually evidenced by the presence of rodent pellets in wheat and by the presence of rodent hairs in flour. The detection of rodent pellets in wheat is simple; only a visual observation is needed. The detection of rodent hairs in flour is a much more complex operation and requires a laboratory technique which it is unnecessary to describe at this point.

Insect infestation in wheat may be evidenced by the presence in the product of live or dead adult insects which can be easily seen by a visual examination. I should say that insofar as contamination of the finished product is concerned, dead insects are just as important as live insects, although of course as long as insects are alive they propagate and the degree of insect infestation is increased thereby.

There may also occur in wheat a type of internal infestation which may not be readily apparent on visual examination. This type of infestation occurs when an insect egg is deposited in or on the berry

and the insect in its early stage of development feeds within the kernel of the berry. Very frequently, however, even though the parent insects have been removed from the grain, insect-gnawed kernels will be present and will serve to flag the grain as "suspect" from the standpoint of internal infestation.

Laboratory Detection

At the present time it is necessary to employ laboratory techniques to measure accurately the extent of internal infestation in wheat. There are two general methods available; one which was developed in the laboratory of Dr. R. T. Cotton depends on staining the affected grain and actually counting the number of such grains in the sample. The other general method depends on grinding the wheat to a coarse granulation, floating off the insect parts, and actually counting them under a microscope. While only two general methods are available, there are many variations of these methods.

If infestation in the wheat is not removed in the milling process, it will pass through into the flour in the form of fragments which can be detected and evaluated by laboratory methods. Incidentally, at this point I should say, at the risk of over-simplification, that efficient mill cleaning practices will probably remove surface infestation, but, so far as we know at the present time, these cleaning methods cannot be depended on to deal adequately with internal infestation. We hope, as our investigation proceeds, to simplify laboratory methods used on wheat so that they may be used by nontechnical personnel in the mill or elevator. This does not seem a hopeless task when we consider what has been accomplished in some other food producing industries. For instance, the Babcock test for determining the amount of butter fat in milk and cream is commonly used by thousands of nontechnical workers in the dairy industry. If a relatively complex method such as the Babcock test can be applied in the dairy industry, may it not be possible by suitable modifications to develop a workable method for use in the grain industry?

Investigational Program

In the beginning, I said that the proposed investigational program was developed after consultation with the United States Department of Agriculture and industry representatives. The proposed program has been reviewed by these agencies, and many very useful suggestions

were made and incorporated in the program which is now under way. The investigation will be carried out over a period of one year in order to observe the influence of seasonal changes. The work will be done over a wide geographical area embodying practically the entire continental United States in order to observe the influence of geographical location of production of wheat or milling into flour. All of the field work will be done in flour mills throughout the country; it includes two broad phases as follows:

1. A mill program to determine the relationship of insect and rodent infestation in wheat to infestation in the flour made from it. This phase of the investigation will evaluate the effectiveness of mill cleaning equipment and procedures.

2. A wheat program to determine the incidence and level of insect and rodent infestation in commercial wheat.

Mill Program

Operations under the mill program involve a study in 16 selected mills strategically located throughout the United States. These mills will be asked to cooperate in the program. Since the purpose of this study is to find out the effectiveness of the cleaning procedure in the mills, it naturally follows that only mills operating under sanitary conditions can be used. Obviously, if the work were done in an insect infested mill, we would not know whether the infestation which might be found in the flour came from the mill or from the wheat.

Each of the 16 mills will be visited every two weeks from April through October and every four weeks for the balance of the year. At each visit samples of crude wheat will be taken. The same lot of wheat will be sampled after it has passed through the cleaning process at the mill. The same lot of wheat will be sampled after it has been converted to flour. These samples will be examined by the methods previously discussed. The information we seek to obtain in the mill program will tell us just what degree of cleaning can be expected from a practical standpoint in a sanitary mill operating on wheat showing various degrees of rodent or insect infestation.

Wheat Program

The wheat program will be conducted in slightly over 100 mills located throughout the United States. The purpose of the wheat pro-

gram is to obtain information on the degree and kind of infestation in our entire wheat production over a period of one year. Geographical, seasonal, varietal, and other variables will be studied. The mills have been selected by a mathematically sound statistical method. The work to be done in each mill will involve merely the collection of one or two samples of crude wheat at intervals of approximately one month for a total period of twelve months. If your mill is not selected for this study, please do not feel that you are being discriminated against. Failure to be selected merely means that the mathematical formula used did not happen to include your mill. It may seem strange to you that some sampling may be done in relatively inaccessible localities. There again it was necessary to use theoretically sound statistical methods of selection in order that our results represent the condition of the wheat throughout the country as accurately as possible. Actually, we are attempting to evaluate this condition by the examination of some 1,600 samples from a total production of some 400,000 cars of wheat.

The milling industry has shown a very high degree of cooperation in the development of our plan and we are quite sure that this spirit of cooperation will be continued as the work progresses. I can pledge to you that in carrying out the work in your mills, our representatives will interfere as little as possible with the normal routine of your establishment. It will be our purpose to make you acquainted with each operation we may have to perform and to explain to you our reasons. As the work progresses, we will arrange to give to each mill the results of our analyses of their own samples, if the mill so desires. If the mill wishes a subdivision of our samples, these will be furnished by our inspectors. If the mill desires to send someone along with our inspectors to collect duplicate samples, such assistance will be appreciated.

Our work will be so conducted and our reports so safeguarded that no information will be given to any mill about the operations of any other mill. As stated above, however, full information will be given to any mill about its own operations.

If any mill is examining samples or making other investigations, we would appreciate receiving the results of such investigations if the mill desires to give them to us. Our laboratories are open to your

technical people. We will demonstrate our methods to you and will be happy at any time to discuss laboratory difficulties with your people.

Report of Investigation

When the investigation is completed, naturally a report will be prepared. Here again, the identity of the various mills concerned will be concealed by a code number known only to the mill concerned. The report will be given to industry representatives. As circumstances may dictate, it may or may not be published in trade or scientific journals.

The information acquired under this program will flow to the Administration for machine tabulation and will not be reviewed from a regulatory standpoint, since only mills which have been found to be in satisfactory sanitary condition will be selected for the mill phase of the work. Should the unlikely occur and any condition develop during the investigation which would render a mill no longer suitable for this type of program, it might become necessary to terminate the investigational program in that mill.

It is a pleasure to meet with you and to discuss plans for a joint enterprise of such vital importance to your industry and to the consuming public. I have thoroughly enjoyed the occasion and look forward with pleasure to working with your industry in the future.

[The End]

Radiation and Public Health

The expanding peacetime use of radiation and its relation to health is being studied in a series of ten courses for state and local health officers, sponsored by the Radiological Branch of the Public Health Service. Among the subjects to be discussed are nuclear radiation, radiation-producing machines, radiation absorption, biological and medical effects of radiation, medical applications or radioisotopes, radiation detection and measurement, disposal of radioactive wastes, and decontamination (Federal Security Agency Release FSA-A29, April 20, 1950).

DEVELOPMENT OF NEW DRUGS

This paper was presented before the Commercial Chemical Development Association, in Chicago, January 18, 1950.

THESE ARE DAYS of ever accelerating change. As normal, educated, sometimes thoughtful human beings, we are aware of these changes. As members of the family of scientists, we are perhaps most aware of man's increasing ability to control his environment and to harness energies other than his own for his own purposes. Man now goes beyond the surfaces of the earth to the depths of the sea or to the heights of the stratosphere. He sees what is invisible and hears what is not audible and feels what cannot be felt. He puts a sensitive finger in the air and learns which way the political winds blow in Formosa or Berlin or Buenos Aires. He razes mountains, fills valleys, causes the desert to blossom as the rose. He sends messages into space and hears the echo back from the moon. The incredible forces within the atom are recognized and, to some degree, harnessed to do his bidding. No man is wise enough to tell what may come of these new-found powers, what further may be added, or what these changes portend. But we are aware, albeit sometimes but dimly, that these changes have come and that they raise new and more complicated questions.

Not so often discussed, nor so well recognized, are the changes man has made in control of his biological environment: changes in medicine, in public health, in therapeutics. At the turn of the century, according to life insurance statistics, a newly born male child had an average life expectancy of about 48 years, and a female child about 51 years. Today the corresponding figures are 65 and 71. In other words,

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nearly 20 years have been added to our expectancy during our own lifetimes. Who would deny that this addition is less significant in its implications, social, economic, political, than the technological advances of which we are probably more aware?

Medicine and Chemistry

There are many elements involved in the development of modern medicine. It would be of interest to point out the analogies between medicine and, for example, the chemical industry. Each has its basic research springing from intellectual curiosity, done without thought of ultimate utility and with a range only limited by the intellectual equipment of the investigators; each has its development, in which the concepts from the research laboratories are translated into terms of utility, with contributions from cognate fields; each has its distribution through various agencies to the ultimate consumer. However time will not permit the development of this idea. Let me pass at once to an area in which chemistry as a discipline and medicine as a discipline have worked together. Specifically, I refer to the development of chemical agents for the treatment of disease. Of course, this is not the only area in which chemistry has been of assistance in medicine. Indeed, a very large part of our concept of man is in terms of his physics and chemistry. Baldwin, in a stimulating little book on comparative biochemistry, speaks of his task as the tracing of the steps "in the evolution of the self-buffering, automatic thermostat which is man."

Drugs Added Since 1900

Since this year, according to some, marks the end of the first half of the century, it has been popular of late to review the accomplishments of the past 50 years, and, in some cases, to prognosticate the future. My own adult professional life does not cover so long a period. Yet I need not go back to 1900 to compass a period in which the developments in drug therapy probably equal those of all the rest of man's recorded history. Let me list in part what has been added. When I was a medical student, fat soluble A and water soluble B were just being talked about as accessory food factors. I will not attempt to say how many vitamins have been added in the intervening period. In the gland field, only dried thyroid, pituitary extract (posterior), and epinephrine were available at that time. Thyroxin was just then being isolated; insulin had not been prepared; the activity of parathyroid had not been separated. We had no androgens or estrogens or active liver or stomach preparations. The adrenal cortical hormones, as well as those of the anterior pituitary, were still to be demonstrated, let alone isolated or studied as to structure. The only gaseous anesthetic was nitrous oxide. Ethylene and cyclopropane were yet to come. Local anesthesia was just coming of age, with cocaine still dominating the picture though there were others. Barbital and phenobarbital were the only barbiturates. Ephedrine was yet to be rediscovered, and the other phenethylamines had little practical interest. The epoch-marking contributions of Ehrlich to chemotherapy were just then in the making. The sulfonamides, marking possibly an even more important contribution, to be followed in incredibly short order by the antibiotics, came at a time when pharmacologists were beginning to feel that the solution of this field of chemotherapy was hopeless. We did not have demerol or amidone or the antithyroid agents or sympathomimetic amines or antihistaminics. While quinine was available for the treatment of malaria, there were none of the synthetics which have proved to be so valuable in recent years. The list is by no means complete, but it will suffice to demonstrate how much has been added in so short a period as one man's life.

Drug Origins

May I go back again to call to your attention the origins of some of today's drugs, in part to emphasize the contribution of chemistry, in part to call attention to the importance of the by-products of research.

As a result of the development of techniques for the isolation and collection of gases, there sprang up in England toward the end of the 18th century so-called "Pneumatic Institutes" where people inhaled various gases for the treatment of disease or sometimes for amusement of themselves or others. At one such institute, a young man, Humphrey Davy, later Sir Humphrey, observed the effects of nitrous oxide which had been made by Priestly about 1776. As a result of his observations he wrote the following, often quoted today:

> As nitrous oxide in its extensive operation appears capable of destroying physical pain, it may probably be used with advantage during surgical operation in which no great effusion of blood takes place.

This was in 1799. I may add that, as so often occurs, no immediate use of this observation was made. Probably it was not possible for technical reasons. Nitrous oxide is a weak anesthetic and can be used alone for only the briefest period. Of course in Davy's time surgery was done in a hurry. Not until 1868 did Andrews, here in Chicago, introduce the combined use of nitrous oxide and oxygen. In the meantime, ether and chloroform had come into extensive use. From knowledge of their properties sprang another series related in action, but serving different uses. A German chemist, Liebreich, in 1869, noted that when he heated chloral hydrate with alkali, chloroform was liberated. Since chloroform is recognized as an anesthetic, perhaps this compound which yields chloroform might also have anesthetic properties. Although, as we now know, the near neutral conditions of the body do not serve to break down chloral hydrate, its trial on this basis led to the discovery of the hypnotic action. From this, of course, developed the long series of urethanes, sulfones, paraldehyde, and the barbiturates and thiobarbiturates.

Role of Chemist

Beginning with the isolation of morphine from opium by the German chemist, Sertürner, in the early eighteen hundreds, many chemists turned to this field. Up to this time most drugs had been crude dried plant products. Indeed the very word "drug" comes from "drogge," dry. From that time there has been a steady succession of reports of isolation of alkaloids and elucidation of structure continuing up to the present time. While the separation out from crude drugs of their active principles did undoubtedly facilitate accuracy of dosage and elegance of pharmaceutical preparation, the advances in thera-

peutics were not proportionate to the effort. However, among the by-products there resulted more than one major contribution. According to Reid Hunt, the starting point of Ehrlich's monumental work, culminating in the introduction of the arsenobenzols for the treatment of syphilis and other spirochaetal diseases, was a purely academic investigation of the vinyl linkage in quinine in relation to its toxicity. The magnitude of this study and of the cooperation of the chemists is indicated by the persistence of the terms 606 and 914 for a long time as synonyms for arsphenamine and neoarsphenamine.

The search of the Germans, after the first world war, for synthetic antimalarials resulting in the introduction of plasmochin and atabrine, the similar search in this country during the second world war in which more than 15,000 substances were screened for antimalarial activity, the cooperative search for morphine-like substances without addiction properties, in which some 600 compounds were studied, these I shall pass with only the comment that they involved the closest cooperation of chemist and pharmacologist. In my personal opinion, this type of direct approach is a very expensive type of investigation, both in manpower and money, which frequently reaches the point of diminishing returns. A field which has been worked and reworked is that of the phenethylamines, resulting in the various sympathomimetic amines. Here the path can be traced from the early studies of German chemists on the autolysis of proteins. The application of similar methods to ergot, which has, incidentally, been such a gold mine for chemists and biological chemists, led to recognition of the amines as among the active ingredients. Indeed for a time these were spoken of as "putrefactive amines." Then came the classical studies of Barger and Dale on the relation between structure and activity. It is a far cry from the autolysis of horse muscle to the benzedrine inhaler. These same studies on ergot yielded both acetylcholine and histamine, although contributions came from other sources as well, such as the close cooperation of Reid Hunt the pharmacologist and Renshaw the chemist on the choline esters. Wholly unrelated in origin were the studies of the substituted urethanes of White and Stedman, of which neostigmine is the result. Eventually again wholly academic interest brought the anticholine esterase activity of this substituted urethane into relationship to the highly potent unstable choline ester from ergot, in attempts at explanation of the method of transmission of a nerve impulse across

a synaptic membrane. The effective analgetic agent demerol is said to have been developed in a search for an antispasmodic. The sulfonamides to which chemistry has contributed so much have their origin in studies of dyes. The antihistaminics of Fourneau, Bovet, Halpern, were originally of purely academic interest, not for their action against histamine but epinephrine. At least, in part, the early antihistamine studies had their origin in an attempt at prevention of gastric ulcers rather than in preventing allergic reactions. Knowledge of the structure of folic acid is dependent on the chemist's study of the pigment of butterfly wings.

Role of Pharmacologist

In listing these fields of contribution of the chemist, I have mentioned, from time to time, the cooperation received from the pharmacologist. As one whose first allegiance has always been to pharmacology, may I be pardoned for taking this opportunity to emphasize to you of the field of chemistry, the potential value of this type of cooperation. Quantitative pharmacology has made very great advances in recent years. It now has the tools in many fields to work with the synthetic chemist to tell him what changes, quantitative as well as qualitative, result from methylation or loss of double bond or opening of the oxygen bridge. Thus he can afford guidance, can be a key member of a program. Without him there may be no means of measuring progress toward a goal which either he or the chemist or both may have set up in the first place. But most of all, more than chemists or pharmacologists or bacteriologists or clinicians, you will need men of ideas, of imagination, men who possess the quality of serendipity. It seems there were once three princes of Serendip, who in their travels were always discovering, by chance or by sagacity, things they did not seek. This word, coined by Walpole, was a favorite of the late Walter Cannon of Harvard, who possessed in himself this quality to a very considerable degree. The expression has been paraphrased by others as: "Chance favors the prepared mind." You will need such men, no matter to what discipline they swear allegiance. Unfortunately there is no magic formula for discovering them. Possession of degrees is no guarantee. Indeed I do not know whether the man who has had one good idea is more apt to have another than the good young man who has not yet struck gold. You will need them and you may search long to find them.

Role of Food and Drug Administration

With this long preamble I come to the matter of the role which a governmental agency plays in this matter of the development of chemicals for drug use. The basic prohibition, under the Federal Food, Drug, and Cosmetic Act, is the interstate shipment of adulterated or misbranded foods, drugs, or cosmetics. This prohibition of course applies to newly developed products as well as to old ones. It thus becomes necessary for the introducer to be certain that his products are properly controlled, that they conform uniformly to their label declaration and carry proper directions for use and warnings against misuse. As his products pass in interstate commerce, they will be sampled from time to time to determine whether he has failed to meet the requirements.

But there are additional requirements established with respect to new drugs; products of the type you have made the subject of this symposium. These requirements are set forth in the "new drug" section of the Act. It is here that there are established the steps which the introducer of a new chemical into medical use or of an old one for a new medical use must take. With respect to new drugs, the law lists among the prohibited acts, the sale or offering for sale in interstate commerce of a new drug for which a new drug application is not effective. This provision of the law is unique. So far as I know, it has no counterpart, although it is my understanding that the Canadian government has just now under consideration a mechanism for attaining the same results.

You will recall that the revision of the old Food and Drugs Act of 1906 was under discussion in the Congress over a period of several years beginning about 1934. During this period of discussion, there occurred a tragic error in judgment with respect to a new drug product, resulting in the loss of more than 100 lives. The use of a vehicle without adequate consideration of its properties resulted in this tragedy. Congress then wrote into the Act under consideration the requirement in effect that before a *new* drug may be introduced it must be adequately studied to show that it is safe, and that a government agency should review the results of this study and should reach what amounts to an administrative conclusion that the drug is safe before permitting this introduction.

This provision has now been in effect over 11 years. During that period more than 7,000 new drug applications have been submitted and

processed by the Food and Drug Administration. In a sense, it is the details of this processing which form the role of the Food and Drug Administration, the subject of my discussion. Many of you are already more or less familiar through personal experience, with the details of the application of this section.

Definition of "New Drug"

A new drug is defined in the Act (I do not follow the legal wording) as one whose composition is such that it is not *generally* recognized, by *experts* qualified by training and experience to evaluate *safety* of drugs, as *safe* for *use* under the conditions of *use* set forth in the labeling. General recognition by experts of safety for use when used as directed, takes a drug out of the new drug category. Failure to meet these conditions makes a drug a new drug within the meaning of the Act. I may pause here to point out that no definition of "general recognition" is given. Nor is there one for "experts." However, the decision as to newness oftentimes is easy. If the substance is, in fact, a new chemical entity, or if it has not hitherto been used in medicine in the method of application or of dosage suggested, obviously the experts will not have the general knowledge necessary for general recognition of safety. No provision is made in the law giving special authority to the Food and Drug Administration to reach a decision as to newness of a drug in the legal sense. We are frequently asked our views, and are quite willing to express them. However, these views are invariably expressed as opinion, based on our own attempts at trying to keep abreast of developments in the field of pharmacology and therapeutics, and the views of specialists in the field. You have the same right to an opinion as we. However, you will readily recognize that if an organization such as ours, whose function in this instance is solely protection of the user against possible injury, expresses reservations regarding the existence of evidence for safety, then the burden of proof should be accepted by the applicant.

Clarification of Definition

There are two points with regard to the definition of a new drug which should be clarified, as there are frequent misunderstandings. The definition as given above relates to safety for use *when used* as directed. In other words, we need to have not only the composition of a drug but the directions for use before us before we can make a final decision.

The second has to do with newness of a drug when it is already on the market. This is a frequent source of misunderstanding. We believe the law is clear here. The second paragraph (Section 201(p)(2)) of the definition indicates that the term "new drug" means: Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions. This is really an extension of the first paragraph of the definition. The fact that an application or two applications have been permitted to become effective and that the drug is commercially available does not of necessity mean that the drug is *generally* recognized as safe for use. Rather, it means that in the opinion of the Administrator of the Federal Security Agency, that is to say, the medical officers of the New Drug Section, the evidence of the safety for use offered by the applicant is adequate to justify a positive conclusion. But "general recognition" is not possible until the drug has been used for a material time or to a material extent so that it has become generally known. In addition, in most cases the evidence on which such a positive conclusion is reached consists of observations which may be as yet unpublished by the investigators, and, therefore, not generally known to the "experts."

Safety of New Drug

Given the decision that a particular product is a new drug, what then are the requirements respecting it? Fundamentally, these are that it be shown to be safe for the indicated use. No definition of what is meant by safety appears in the Act. In fact, it does not seem to be possible to write a satisfactory definition. In Webster's unabridged dictionary, safety is defined as freedom from danger or hazard. But freedom is relative. Every physician knows that when he elects to use drugs in the therapy, diagnosis, or prevention of disease he must, consciously or unconsciously, weigh the possible hazards against the potential value of the drug for his purpose. As we have pointed out elsewhere, he does not hesitate to employ general anesthetics or local anesthetics, digitalis, insulin, antitoxins, or radium if the need exists, even though, in an absolute sense, none of these substances can be said to be safe. We, in the Food and Drug Administration, have taken the position that a maximum of safety

should be the goal, and that this maximum of safety is approached when the physician is fully informed with respect to the drug he chooses to employ.

Study of New Drug

This means then that each application should carry a sound pharmacological and toxicological study. Frequently a considerable part of this will have been provided by the screening tests which have been applied in the laboratory, the results of which have led to further study and decision to put the drug into the development phase. These studies will have placed it in its group, pressor amine, stimulant to smooth muscle, mydriatic, local anesthetic, antihistaminic, and will have related it at least in a semiquantitative fashion to other members of the group. (For economy of money, manpower, material, these screening tests are limited. It is one of the problems of administration of a research laboratory to establish the point of diminishing returns in a screening program, as well as in the synthesis of related compounds by the organic chemist.) Given the general characterization of a substance that results from this process of selection, there remain other problems for the laboratory. Is it effective in reasonable amounts? What is the margin of safety, or relationship between effective dose and toxic dose? How does this ratio compare with those for other substances of similar therapeutic action? If the substance is to be given at frequent intervals, what is its toxicity when so given? Chronic toxicity determinations, so called, are particularly important when the drug may be given for long periods of time. How is the drug test absorbed? How is it excreted? Does it possess local irritating properties? Is it sensitizing? What effects follow overdosage? How may these be treated? These illustrate but do not delimit the information required from the laboratory, from work on laboratory animals. The Food and Drug Administration has expressed its general views with respect to what is covered by a thorough study, but does not ordinarily like to comment on a specific program in advance for the reason that it thereby would be committed to approval of the program as completed. But these represent only the first step. Usually, whether it be so labeled or not, the next step is a pharmacological study on the human animal. Working cautiously, with due regard to all the data obtained from the laboratory, the clinical pharmacologist makes his first human studies. He must learn whether the results

obtained on other animals can be applied to this one. Is the drug still effective? Benzyl penicillin proved to be in mice but not in man. Are there symptoms in man not shown by laboratory animals? A barbiturate which looked very promising in the laboratory was discarded after two cautious trials in the human revealed tremors induced by it.

Importance of Initial Studies

Out of these early clinical studies come two findings: (1) whether or not the drug justifies further study; (2) if so, the dosage, frequency, route of administration, signs of toxicity to be watched for. These studies must define the procedures to be followed by others as clinical trials expand. One sees little discussion of these initial studies, but for organizations such as your own, they are both relatively difficult to obtain, and of the greatest significance to your ultimate program. Their very nature is such that they must be undertaken with every possible safeguard by way of protection to the subject. They may and not infrequently will result in prompt dropping of the project so far as the particular compound is concerned. Most collaborating clinicians do not care to do screening, which is, in fact, what we have been in part describing. Further, the clinical investigator cannot depend too greatly on the dosages from the laboratory, and may find the clinical trials not confirming the laboratory findings because of failure, for one or another reason, to reach effective dosage levels. Finally, after the initial clinical trials, comes the more extended use by more than one investigator which is needed to establish the value of the new agent, as well as the type and frequency of the side reactions which may result. Neither human beings nor laboratory animals react always in identical fashion to a drug. There are both quantitative variations in degree of response, often spoken of as variations in sensitivity, and also qualitative variations in type of response, sometimes called idiosyncrasies, sometimes apparently developed by repeated administration, and called sensitization. Whatever they be called, and whatever their explanation, it is important to have enough cases of actual trial to give some index as to both frequency and severity.

Directions for Use

We have not mentioned the word safety for several pages. The requirement of the new drug application reads "full reports of all in-

vestigations made to show the safety" for use. However the law also has the requirement that directions for use be supplied. These will have to do with the most effective way of using the substance as well as the safety. Actually you would find it difficult to persuade physicians to use your products unless they give promise of being effective. Safety without concomitant efficacy would be of little value.

Statement of Composition

The pharmacological studies, both on laboratory animals and man, and the clinical studies make the "full reports of investigations made to show whether or not such drug is safe for use" called for in the Act. Other material required consists of a detailed statement of the composition of the drug and of its components, the manufacturing and control facilities and procedures used in making the drug, a sample and the label and labeling. It scarcely seems necessary to comment on the requirement as to statement of composition in these days of informative labeling. However, I may comment briefly on the requirement regarding details of manufacturing and control. These are tied directly to the question of safety. Obviously the decision as to safety relates to a specific drug. This decision cannot be carried over to some other substance not covered by the report. And unless the introducer submits evidence of his ability to manufacture successive lots of uniform potency and demonstrates that his methods and facilities for control will bring to his own attention failure to maintain the identity, strength, quality, and purity of the product for which he is applying, then it becomes difficult to reach a conclusion that the product is, in fact, safe for use.

All of this material is sent to us in duplicate. If technically complete, it is filed and the applicant is notified of the filing date. An application not otherwise handled according to the law becomes effective automatically 60 days from the date of filing. If we require further time for study, this can be extended to 180 days by going through certain formalities.

Action on Application

Once filed, the application is before us for study. The nature of this study and the time taken will depend on the magnitude of the problems, as well as on the adequacy of the information given. Since no man of himself is wise enough to be competent in all the fields

covered, we in the New Drug Section call on our colleagues for assistance. This means, for example, that pharmacological studies may be reviewed by our Division of Pharmacology, antiseptic or fungicidal claims and the information back of them by our Division of Microbiology, control procedure by Chemical Branch, and so forth. Unless further information is called for, the application is permitted to become effective, and the applicant so notified without waiting for the completion of the 60 days established in the law. More often it happens that there are points which require clarification. It may be that we feel that the experimental data do not justify a conclusion on our part that the drug is safe for use. The deficiencies will then be pointed out, often in personal conference. Meantime, as a rule, the applicant formally withdraws his application, to be resubmitted without prejudice when the additional data are accumulated. It has been a source of satisfaction, I am certain, to all of those who have worked in the New Drug Section, certainly it has been to me personally, that the give and take in this matter of the new drug application has been on a basis of mutual respect and understanding, with a common aim between us of insuring safety to the ultimate user.

It might be added that in our effective letter we usually take the opportunity to express our views with respect to the claims made in the brochure. If we are not in complete accord, we indicate the fact. Since the purpose of the new drug section of the Act is to establish safety and not efficacy, we may not refuse to make the application effective because of our differences of opinion regarding the merits of the product. We do, however, make it clear to the applicant that he must assume the responsibility for whatever claims he may make.

Thus we have spelled out the role of the Food and Drug Administration in the development of new drugs. It may have seemed to you as you listened to me that most of the time I have been talking about requirements that would exist whether there was a Federal Food, Drug, and Cosmetic Act or not. If so, I have been reasonably successful in my presentation. For, in the long view, what the Act in fact does is to supply sanctions to support an obligation which already exists to insure that your products may be safely used. In most cases, you will recognize that not only moral obligation but enlightened self-interest virtually compels you to carry out the requirements of the law. **[The End]**

Indiscriminate Sale of Dangerous and Habit-Forming Drugs

• • • • • • • • • • • • • BY GEORGE P. LARRICK

SOME TIME AGO the physician in charge of a large municipal venereal disease clinic called at our offices. He described with enthusiasm the increasing success which they were having in case-finding; and he was particularly pleased with the results being obtained with some of the more modern drugs used in venereal disease therapy. He reported, however, that in a number of cases which had come to them recently they had undertaken treatment with one of the sulfonamides. The patients did not respond and he, in consultation with his colleagues, had reached the conclusion that the organisms had become resistant to the medication. Persistent inquiry of the patients brought forth the information that they had undertaken self-treatment before reporting to the clinic. The patients did not know the name of the medicine they had taken but the clinic physician had procured a few tablets from them. Anaylsis revealed that they were sulfathiazole. Most of the patients were unwilling to reveal where they had purchased the medicine but one of them did name a drugstore in a slum district. We undertook an investigation of this drugstore. In each case the investigator would visit the drugstore and seek a private conversation with the pharmacist. He would ask for some medicine for gonorrhea. The druggist's reply in each instance was that he had three types of medicine for this condition: the first treatment was fair and cost $2; the second treatment was better and could be had for $5; but if they wanted a sure-fire cure they would have to part with $9. During the course of the investigation, we bought

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all three treatments and all of the purchases were witnessed by food and drug inspectors. The first was an old-fashioned mild silver protein preparation, the second treatment was sulfathiazole, but the sure-fire cure was penicillin. In no instance, however, was the amount of medication and instructions provided adequate to deal properly with the average case.

This investigation led to a criminal prosecution in the Federal court and the illegal practices ceased. This case is characteristic of one type of problem in the indiscriminate sale of dangerous drugs, which unfortunately is not uncommon.

Sale of Barbiturates Without Prescription

The warden of a midwestern penitentiary visited one of our field district offices. He explained that a serious problem in any penal institution involves the difficulty of preventing the inmates from surreptitiously gaining access to a wide variety of drugs such as narcotics and barbiturates, as well as amphetamine and other drugs having a similar stimulant action. He reported that his problem at the moment involved the extensive sale of barbiturates within the penitentiary. He had obtained some leads to the possible source of supply and suspected that interstate commerce was involved. He therefore sought our cooperation.

The trail led back to a large mail-order drug house in New York. The firm did a legitimate business with many doctors, but when an order was received they did not bother to make sure that the order was from someone who had a legitimate right to the medication. In this particular instance it developed that phenobarbital tablets were being shipped regularly to a farmer who lived close to the prison. A

trusty in the penitentiary had been given considerable latitude. He would stop his truck, en route to the city, in a nearby woods and would then proceed surreptitiously to the side of a farmhouse where he would knock four times on a wall beside a window. A substantial sum of money and a bottle containing a thousand barbiturate tablets would then change hands. Investigation disclosed that this firm was selling a variety of dangerous drugs in wholesale lots to taxi drivers, owners of houses of prostitution, and, in fact, to anyone who sent in an order accompanied by a check.

This case, too, led to a criminal prosecution. The firm discontinued all operations in drugs of this sort.

Jurisdiction of Act

The present Federal Food, Drug, and Cosmetic Act became a law in 1938. It was our opinion that this law could be applied to foods, drugs, and cosmetics from the time they were offered for interstate shipment until they reached the ultimate consumer. This viewpoint was by no means universally shared by competent lawyers. The opinion was widely held that Federal regulation could extend only to interstate shipments of drugs, for example, until the time they reached the wholesaler at destination. In other words, these lawyers asserted their view that once a food or drug reached the wholesaler at destination, then any further regulation of it would necessarily be exercised exclusively by state and other local authorities. Although a number of cases were brought which raised this question, it was not decided with finality until early in 1948.

During 1946, we received complaints that military personnel stationed in a southern state were undertaking self-treatment for venereal diseases. The physicians in charge of V. D. work at the camp reported that inadequate self-treatment was seriously interfering with their control program. We made an investigation in the small towns adjacent to the camp and found that several retail drugstores were freely selling sulfathiazole without prescription to military personnel. The drug had been shipped in interstate commerce under a label which clearly stated that it was to be used only on the prescription of a physician. Nevertheless, the pharmacists removed the sulfathiazole from this package and sold it, without a physician's prescription, in small envelopes and prescription boxes.

Jurisdiction Over Retail Sales

Criminal informations were filed against several drugstore owners. One of them contested the action. The sulfathiazole involved had been manufactured by a large firm. It had been shipped to its branch warehouse in the southern state. From there it was transported to a wholesaler, and later still, it moved to the retail pharmacy. The lawyers for the defendant took the position that Federal jurisdiction extended only to the time that the shipment came to rest in the manufacturer's branch warehouse in the state at destination. Judge T. Hoyt Davis held that the Federal Food, Drug, and Cosmetic Act did apply to the transaction in the retail store. The case was appealed to the United States Circuit Court of Appeals at New Orleans. This court reversed the district court's decision and held that the Act conferred no jurisdiction over retail transactions of this sort. The case reached the Supreme Court and was decided on January 19, 1948. The Supreme Court held that the purpose of the Food, Drug, and Cosmetic Act is to safeguard the consumer by applying the Act to foods, drugs, and cosmetics from the moment of their introduction into interstate commerce all the way to the time of their delivery to the ultimate consumer. Almost simultaneously, the Congress added an amendment to the Act which even more clearly set forth the congressional intent to prevent adulteration or misbranding of foods and drugs while in interstate commerce or at any time thereafter.

It was almost ten years, therefore, after the Act was passed until it was authoritatively known just how far its provisions extend. We had pursued a quite conservative course in dealing with the indiscriminate sale of dangerous drugs during this time of uncertainty. We had sought the widest dissemination of information to retail druggists concerning our opinion of the Act's scope, and we had brought a limited number of cases in the Federal courts. Some of these were in Texas and all of them have involved serious public-health problems.

After we learned authoritatively that Federal jurisdiction did extend to the illegal retail sale of dangerous and habit-forming drugs, we accelerated our investigations in this field and have brought an increasing number of cases in the Federal courts.

The most extensive abuses occur in the sale of the barbiturates. These sleeping pills, tablets, and capsules are popularly known among addicts as "red birds," "goof balls," "yellow jackets," and by many

other names. We have made arrangements with coroners, emergency hospitals, police departments, and a number of other agencies to report to us instances of serious abuses growing out of the use of dangerous and habit-forming drugs. Case after case has come to our attention where an individual who perhaps initially used barbiturates in moderation for insomnia eventually became addicted to their use, and, in literally thousands of cases, the usefulness of the individual to himself and to society was completely destroyed. Accidental deaths, suicides, and many other tragic sequelae are common results from the ill-advised consumption of sleeping pills. There is still a large problem involved in the control of the sale of barbiturates without prescription, but it is our opinion, based on extensive investigation, that a still greater problem exists because of the repetitious unauthorized refilling of prescriptions.

Unauthorized Refilling of Prescriptions

Case histories taken at random show, for example, that a woman in a midwestern town, who was the mother of three children, presented herself voluntarily to a hospital to be cured of barbiturate addiction and alcoholism. A check on the source of her supply of barbiturates revealed that a prescription dated August 28, 1948, for 30 seconals, ¾ grain, had been refilled 16 times in three months. A total of 500 capsules was dispensed on an original prescription calling for only 30. Another woman who had been mildly ill from hypertension was found dead in her bed. There were three empty prescription boxes on her table. A check at the pharmacy, whose name was shown on one of the empty prescription boxes, showed that she had originally had a prescription for 20 nembutal capsules, 1½ grains. This prescription had been refilled 23 times in six months. The physician who had originally prescribed the 24 tablets was totally unaware of the refilling and was very much distressed to learn that this woman had obtained a total of 740 capsules on his original prescription for only two dozen.

The problems involved in the indiscriminate distribution of dangerous and habit-forming drugs is not restricted to the barbiturates. The sulfonamides, high-potency vitamin D capsules, amphetamine, thyroid, stilbestrol, estrogens, and androgens, as well as a host of others are involved. We have also found extensive commerce in drugs popularly believed to be capable of terminating an unwanted pregnancy.

A physician in Georgia reports the case of a young schoolteacher who came to him in a most unfortunate condition. Her difficulty arose because she was able to obtain repetitious refills of propylthiouracil. A middle-aged housewife consulted a clinic because she believed she had heart trouble. She had been vomiting profusely, was completely exhausted, and was wildly excited. She complained of her heart pounding and turning over; her heart beat very irregularly. Questioning elicited the fact that she had been taking some capsules for her heart. She had found an empty bottle which had contained a medicine prescribed by a physician who had attended her several years before. She had had it refilled without consulting anyone. The medicine involved was a digitalis preparation.

Recently we were preparing the evidence for presentation in a case where a firm was engaged in the wholesale distribution of estrogenic and androgenic medicines without prescription. This firm not only did a local business in a retail drugstore but conducted extensive distribution through mail orders. They had placed their advertising in a number of publications of national distribution. To show the inherent dangers in this practice, we visited a number of leading endocrinologists, gynecologists, and urologists in the area. The physicians told of instances where women had received legitimate prescriptions for estrogenic medication. They had repetitiously refilled their prescriptions and eventually had gotten into very serious difficulties involving extensive bleeding, and in some cases the physicians asserted their opinions that the growth of breast or genital neoplasms had been stimulated. It also appears to be established that the injudicious use of androgens is capable of causing impaired male fertility.

We are glad to know that the last legislature of this state has enacted a law which deals with some of the dangerous and habit-forming drugs. It appears to provide that the drugs named therein shall not be sold in Texas without a prescription, and that such prescriptions cannot be refilled.

There is, in our opinion, an important public health problem involved in the indiscriminate sale of dangerous and habit-forming drugs throughout the United States. This distribution involves, first, the sale of such drugs without a prescription; but secondly, and in our opinion more importantly, the promiscuous unauthorized refilling of prescriptions.

Educational Operations

We are seeking to lessen present abuses by both educational and regulatory operations. Our educational efforts are being supported by many local and national leaders in pharmacy. We have repeatedly advised the pharmacists of the nation that, in our opinion, a prescription is a written expression of the physician's will and purpose that a patient be furnished a specific quantity of a drug for use as the physician directs. We believe that no amount of the medicine greater than that called for in the original prescription should be sold to the patient without the physician's permission. In other words, without a specific authorization to refill, the special legal and professional status of a prescription expires on the first filling. Once filled, such a prescription has the same value as a check on which a bank has made payment.

The problems of enforcement in this field are extensive. It will take the combined resources of local and Federal enforcement officials and representatives of the pharmacy profession to prevent the harm which now flows from the indiscriminate sale of dangerous and habit-forming drugs. **[The End]**

Grocery Trade Practice Conference

The Grocery Industry Committee held another meeting on May 9, 1950, in Washington, D. C., to continue formulation of a draft of proposed trade practice rules for the industry. Among the proposals discussed at an earlier meeting were certain suggested rules intended to embody legal requirements relating to the following subjects: prohibited price discrimination, selling below cost, geographical price-cutting, false invoicing, and exclusive deals, to name a few.

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PLANT INSPECTIONS

I WELCOME this opportunity of discussing with you one of the most important phases of the work of the Food and Drug Administration: plant inspections.

Let us consider first what is in the inspector's mind when he comes to your plant, introduces himself, and says, "I would like to make a factory inspection." What ulterior motive might there be to the visit? What diabolical scheme may be going around in his mind? Is he a friend, or a necessary evil to be tolerated but not helped; or is he, perhaps, an undesirable interloper to be resisted?

I will not keep you in suspense by delaying the answers. We think you should welcome the Food and Drug inspector. He comes for the obvious purpose of determining whether your manufacturing operations meet the requirements of the Federal law. Simultaneously, he makes a scientific evaluation of procedures, which generally is of value to the manufacturer who avails himself of the inspector's observations; observations which perhaps have escaped notice by those in everyday contact with the plant.

We do not regard ourselves as infallible in the field of factory inspection; nor do we claim to have all the answers to problems which arise in modern drug manufacture. Much of the information we have acquired comes from you through your wholehearted cooperation and patience with the inspector in the past. If the Food and Drug Administration has acquired any credit in enforcing the national drug law,

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that credit goes in no small measure to the very drug industry which is influenced by the law; to you and your competitors who have furnished a favorable environment for the development of our personnel.

Policy

The Food and Drug Administration follows a policy of forthright dealing with industry. At the conclusion of an inspection, the inspector is glad to call the attention of a responsible representative of the firm to any practice or condition which he believes may yield an adulterated or misbranded product. Where possible, he will be glad to recommend corrective measures.

He will not attempt to comment on questions of therapeutic claims or on questions which require review by medical officers, or other personnel in our Washington offices.

Before the inspector comes to your plant to make a control factory inspection, he prepares himself to do the job as completely and expeditiously as possible. He studies your catalog to determine the types of products manufactured and the difficult manufacturing operations he may encounter. He may study reference material on bacteriology, chemistry, pharmacology, toxicology, or related subjects, to refresh his memory on elusive details of drug manufacture. This preliminary work is not substituted for alertness and careful observation in the plant.

Preparation of Master Formulas

Some of the things the inspector considers when he is at your factory are the preparation of master formulas and the care taken to see that they are prepared by competent personnel and transcribed into batch manufacturing formulas without error. Some time ago, we investigated a report that an oral antacid preparation caused nausea, and we found that the master formula used by the company, an established firm with many years of experience, was carried in the head of one of the officers. He happened to be sick when it came time to produce the batch in question. A trusted employee of the firm proceeded to his bedside and wrote the formula down by hand as it was repeated by the officer. The sick man's recollection was good, but the employee's writing was not. Later as he manufactured the batch, he used 50 gms. of saccharine rather than five gms. usually employed. The tail of a handwritten "G" in the line above looked like an "O" after the "5." The firm was put to considerable expense and embarrassment through its failure to follow an orderly scheme of recording master formulas and making them available to the manufacturing department.

Storage and Handling of Raw Materials

We are interested in the storage and handling of raw materials and in the avenues whereby they may become mislabeled or contaminated. The drug manufacturing industry has taken outstanding steps to improve the sanitary conditions in its plants. As you know, the Food and Drug Administration was greatly impressed with the recommendations of the combined pharmaceutical contact committee sponsored in part by your association.

Also, the inspector may investigate the manufacturing and labeling departments to determine whether they are conducted in a manner likely to produce the desired end product or, conversely, in a manner likely to lead to errors. One phase of the manufacturing operation which requires continual alertness is the control of labeling of the finished retail packages. Occasionally we find that labels for different products which are similar in size, color, and general appearance are stored in such a manner that they may become intermingled at any time. In investigating an instance in which bottles of turpentine were labeled as containing castor oil, the inspector discovered castor oil labels in a

package of turpentine labels in the label storage room. Even in well-managed factories where label storage is handled with care, there is danger of an occasional mix-up of labels as they come from the printer.

Manufacture of Injections

Investigation of the manufacture of injections is one of the most exacting operations confronting us; and, of the injections, those which cannot be autoclaved are particularly troublesome. There is a dearth of information as to the conditions under which sterilization procedures other than autoclaving may fail to give the desired result; we do know that upon occasion they fail and a contaminated solution is produced. The trouble may be due to a chance heavy inoculation of the bulk solution with bacteria, to dirty equipment or ampuls, or to the human element in the factory.

An employee may use the wrong chemical in compounding the solution, or may designate as sterilized a tray of ampuls which has not gone through the sterilizing procedure. To guard against and detect such slips, it is essential to set up adequate control measures which give a good check on the fitness of the finished, labeled drugs as they await shipment.

Testing for Sterility

By far the greatest trouble in the manufacture of parenteral solutions in the past two years has been the distribution of nonsterile injections. Generally, the manufacturer has examined the injection prior to shipment without detecting the presence of living bacteria. How can we explain this apparent deficiency of laboratory control in some of the best plants? It may be due in many cases to (1) reliance upon sampling procedures, previously regarded as adequate, which are now recognized as ineffective, and (2) reliance upon inadequate biological testing procedures. Let us look at the sampling technique for a moment. How should you sample a batch of a thousand ampuls of an injection for sterility testing? If you make adequate bacteriological examination of three ampuls from the batch, the statisticians tell us that three times out of 100 you will fail to detect lots which are 70 per cent contaminated; 12 times out of 100 you will fail to detect lots which are 50 per cent contaminated; and 34 times out of 100 you will not detect lots which are 30 per cent bad. Suppose you select from the 1,000 ampul batch five ampuls for sterility testing; 17 times out of 100

you will pass a lot which is 30 per cent contaminated. If you test ten ampuls from the batch, you will pass as sterile one of every five lots which is 20 per cent contaminated. If you test 20 ampuls, you still will pass one out of every ten lots which is ten per cent contaminated. Essentially the same figures hold for larger batches. For smaller lots the figures are somewhat different, but not enough so to change the fundamental approach to the problem.

Obviously, the manufacturer cannot test all of the ampuls in each batch for sterility, nor can the government test 100 per cent of each shipment. In practice, we try to balance the theoretical ideal with practical considerations. We prefer to have 20 ampuls from a given batch for the sterility test, but when this number is prohibitively expensive or otherwise unavailable, it is necessary to be content with a lesser number. Quite often our views as to the number of ampuls which should be checked in our laboratory are influenced by the adequacy of the sample originally collected and examined by the factory.

Bacteriological Test

Now let us consider the adequacy of the bacteriological test as applied to the control sample. The best test, theoretically, would be to use the entire contents of each ampul.

Here again we must be practical; because of the large volume of the solution to be tested or its bacteriostatic nature, it often is necessary to use only a portion of an ampul for each inoculation. However, an easy method of increasing the reliability of the test under these circumstances is to inoculate more than one tube of bacteriological test medium from each ampul. Our bacteriologists like to inoculate three tubes of medium from each ampul under test, using the largest volume of inoculum possible, and where the presence of a bacteriostatic agent requires the use of a very small inoculum, say ½ cc., the bacteriologists plant more than three tubes from each ampul. There is little doubt that many of the cases of nonsterility in injections, which recently have come to our attention, involve slight contamination not uniformly distributed throughout the batch; under such circumstances you do not do yourself justice if you rely upon a test which determines the sterility of only a few drops from each ampul.

If the control laboratory were the only check which a manufacturer has on the fitness of his parenteral solutions, one might conclude that the chances of shipping contaminated products are very high. Fortunately, in the well-operated factory, careful manufacturing control assures the purity of the vast majority of the batches and the laboratory serves as an additional safeguard to pick up the isolated case in which manufacturing control breaks down. The laboratory has great value, also, as a measure of the effectiveness of manufacturing control. For example, bacteriological tests made at various points in the production of an injection which must be sterilized by filtration, let us say tests on the bulk unsterilized solution, on the bulk solution after filtration, and on the solution after the filling operation, may disclose the use of a raw material so heavily contaminated as to place an undue strain on later operations; or the tests may reveal the need of changes in the fineness of the filter or in the technique of filtration or filling.

Similar studies should show whether it is safe to rely upon tyndallization to achieve sterility where a bacteriostatic agent is present in the injection. Is it possible that some of the bacteriostats in common use merely inhibit growth of spores during the tyndallization process, without killing them? If so, do the spores then develop at leisure in the solution after it has been placed on the shelf awaiting shipment? We do not know the answers. Such questions appear to deserve exploration by the drug industry.

Study of Control Operations

In connection with our inspections of drug factories and examinations of samples from drug shipments, we hope, in addition to determining that there is compliance with the Food, Drug, and Cosmetic Act, to be able to direct your attention and ours to any weak spots in manufacturing and control operations which are apparent and to important questions whose answers may warrant some fundamental study by the industry, so that industry and the government will be able to anticipate emergencies and to prevent them.

Recall of Dangerous Drugs

The increasing effectiveness of well-integrated manufacturing and laboratory controls, which we observed in recent inspections, inevit-

ably leads to the conclusion that the American consumer receives better drug products than ever before. This is confirmed by a marked drop in the detection of lots of drugs which were dangerous and had to be recalled from the market. During the twelve months ending April 26, 1949, there was an average of three recalls of potentially dangerous drugs per month, and during the next six months there was an average of two recalls of potentially dangerous drugs per month. In the past four months, however, there have been only two such recall programs. We do not know why there was a flood of drug recalls in 1948 and 1949. It may have been occasioned, in large measure, by the fact that manufacturers were becoming more aware of modern methods of detecting contamination of their products. Consequently, they were locating a greater percentage of bad lots than ever before. It may also be due in part to the fact that inspectors of the Food and Drug Administration today are far more competent to make a scientific evaluation of conditions in the factory than ever before. There is no doubt that drug controls generally have been tightened up during the past 24 months, and that when potential danger is at hand it generally is detected and dealt with promptly.

It has been almost 12 months since the Food and Drug Administration found it necessary to go to the press and radio to warn consumers of the existence on the market of a potentially dangerous drug. This is because you have been more alert to detect the first signs of danger and to remove stocks which might cause trouble. It is because your complaint files have been studied more carefully to determine whether there is any validity to those complaints which you receive, and because your coding systems and records of distribution have been maintained in such fashion that, when a potentially dangerous drug appears on the market, you are able to determine where the entire lot is and to reclaim it without delay. This is as it should be. We do not like to publicize the existence of dangerous drugs on the market any more than you like to have it publicized.

Another reason that publicity has not been required recently is that more and more manufacturers come to the Food and Drug Administration the moment they learn that something is amiss to solicit our advice in the planning of a recall program. Our experience in the removal of dangerous products from the market enables us to offer valuable advice to the average drug manufacturer who is confronted

with this problem, especially the first time he conducts a recall. You have nothing to lose by consulting the Food and Drug Administration at the earliest moment. There probably is no extensive recall of a drug today which fails to come to our attention sooner or later. We are in a much better position to assist you if we can participate in the planning of the recall at its outset, rather than weeks or months later.

I appreciate the opportunity of meeting with you. The Food and Drug Administration appreciates the cooperation which you have extended to its inspectors. Let me suggest that, at the close of the next inspection of your factory, you sit down with the inspector and ask him any questions which may have arisen about your operations or our procedures. He will try earnestly to give a responsive reply. After all, we are united in our desire to see that the American public gets pure, wholesome drugs. **[The End]**

Economic Changes In World

A picture of economic changes in the world since 1928, as presented in the new United Nations *Statistical Yearbook*, shows that although production of most basic foods, materials, and commodities has steadily risen since the end of World War II, it is not substantially above the 1928 level in most instances, and in several cases is below. World production of wheat, rice, oats, and potatoes is down while that of cotton, wool, coal, and zinc is about the same. Rubber, petroleum, rayon, and aluminum production has increased substantially (*United Nations Bulletin*, February 1, 1950).

user when used as directed. The antihistamine ingredient in Inhiston is listed in the complaint as "1-phynyl-1-(2-pyridyl)-3-dimethylaminopropane," each tablet containing 10.31 milligrams.

False advertising of C.S.A. Tablets as a cure and an adequate, effective, and reliable treatment for arthritis and rheumatism is charged in FTC Docket 5765. Representations that the tablets are a new discovery of medical science, that they may be used over a prolonged period of time without harmful effects on the body, and that they will not cause gastric distress are also questioned by the complaint. The ingredients of each tablet are listed as calcium succinate (2.8 grains) and aspirin (3.7 grains plus excipients).

Representations that "Miner's Friend" is of value in the treatment of aches, stiffness, flatulence, heartburn, biliousness, poor appetite, upset stomach, poor digestion, nervousness, dizziness, or poor complexion have ended by stipulation (Stipulation 7970).

A drug company has agreed to cease representing that "Eno's Effervescent Salt" has any therapeutic efficacy in the treatment of constipation or gastric hyperacidity in excess of the relief afforded by a laxative antacid to a temporarily constipated condition or a temporary hyperacid condition. The corporation further agrees to refrain from claiming that the product will enable one to keep cool or have a refrigerant effect on the body (Stipulation 7975).

Macaroni.—A macaroni manufacturer has agreed to cease representing that his products do not contain starch or carbohydrates; that they contain more protein than meat or are more nutritious than meat; that no other macaroni contains Vitamin B 1 or iron; that the products are a perfect food or perfectly balanced foods; that they have therapeutic value in the treatment of any disease; that they possess antiketogenic properties; or that starch fatigues the digestive organs (Stipulation 7974).

Hair and Scalp Preparations.—Misrepresentation of the effectiveness of a hair and scalp preparation is alleged in FTC Docket 5743. The complaint states that the product is not a cure or effective treatment for dandruff or unhealthy scalp or hair conditions, and will not promote the health of the scalp or hair as represented in radio and periodical advertising.

A company manufacturing "308 Hair Preparation" has agreed to refrain from representing that its product is a cure for dandruff or dry, scaly, itchy or oily scalp and a preventative for falling hair (Stipulation 7967).

Representations that a line of medicinal and cosmetic preparations will prevent baldness are challenged in FTC Docket 5757. Claims that the product will penetrate below the skin surface and destroy bacteria and bacilli, and that it will reopen clogged hair passages, energize hair papillae and make sluggish blood circulation in the scalp normal are also alleged to be false and misleading.

Hair Removing Device.—A complaint charging false and misleading advertising of a hair-removing device was dismissed in FTC Docket 5589, due to lack of adequate evidence.

Food and Drug Products.—Nine food and drug products were the object of an order to cease and desist in FTC Docket 5455, which charged false and misleading advertising. Forbidden claims are: that Tasty Soup Mix possesses energizing properties beyond those of a nutrient; that Garlic-Tabs possess tonic or therapeutic properties other than those

of a carminative agent; that Laxa-Tabs are a natural regulator or eliminant possessing tonic or astringent properties; that Carrot-Tabs are an aid to digestion or have therapeutic value for a putrescent condition of body tissue; that Mucin-Oide is an effective stomach preparation; that Iron-X treats an iron deficiency; that Vitman B Ration is of more value than as a dietary supplement in vitamin-deficient diets; that Erbecell relieves dyspepsia; and that Wheatex-B contains significant amounts of Vitamin-B complex, iron, calcium, or phosphorus.

Carbonated Beverage. — An imitation grape-flavored carbonated beverage company has agreed to eliminate advertisements using such unqualified terms as "Graport," "grape flavor," "winey flavor," or "winey muscadine flavor" to describe its product (Stipulation 7950).

Ozone Generator. — Representations that the "Atmoray Ozone Generator" produces enough ozone to substitue for sunlight in elimination of contamination and that it will eliminate airborne bacteria, carbon monoxide gas, and excessive carbon dioxide gas are questioned in FTC Docket 5749. Facts omitted from advertising, according to the complaint, are that: "Inhalation of excessive amounts of ozone may result in severe irritation of the respiratory organs. In order to avoid injury, the concentration of ozone should not exceed one part per million parts of air where exposure is for prolonged periods of time. Proximity to the device should be avoided."

Optical Goods.—Use of a "self-testing" outfit by a layman to test his own eyes and prescribe corrective lenses in promotion of the sale of eye glasses is challenged in FTC Docket 5759. According to the complaint, "there is danger in the use of the apparatus because of its inability to detect and measure astigmatic conditions, muscular conditions, and conditions where the two eyes give different images in either size or contour: . . . inadequate correction of these conditions, as well as inadequate correction of nearsightedness or farsightedness, may result in nervousness, headache or other discomforts."

In the State Legislatures

Barbiturates.—Barbiturates may be sold in **Kentucky** by a licensed pharmacist, only upon the prescription of a practitioner. The label must show the name and address of the pharmacy or pharmacist, the name of the person for whom the drug is prescribed, the date of filling the prescription, and if for an animal, the specie and the owner. The dispensing of barbiturates by a practitioner to a patient is governed by the same conditions. The law regulates the sales by wholesalers and manufacturers to pharmacists, practitioners, hospitals and institutions where distribution is directed by practitioners, Federal, state and local governments, manufacturers and other wholesalers, and regulates their use for lawful research, teaching or testing. A preparation containing barbituric salts or barbituric acid derivatives is exempt from the law, if it is intended for use as a throat spray or gargle or for external application and contains, in addition to the derivatives, some other drug rendering it unfit for internal administration; nor does the law apply to a preparation which contains a sufficient quantity of another drug to cause it to produce other than a sleep-producing action (H. B. 262, approved March 25, 1950).

Eggnog.—Eggnog is now defined by a **New York** law as a "clean wholesome food product made with milk products, eggs, harmless flavoring, with or without harmless coloring and with or without added stabilizer compound composed of wholesome, edible material." It must contain not less than eight per cent milk fat, nor more than one half of one per cent stabilizer and not less than one per cent egg yolk solids (A. B. 2439, approved April 1, 1950).

Electrical therapeutic instruments.—California has directed an Assembly interim committee to investigate the need for legislation regulating the use of electrical therapeutic instruments in medical treatment. (H. R. 19-X, adopted March 31, 1950).

Ice cream.—Ice cream, for **Massachusetts** consumption, must not contain more than one half of one per cent stabilizer, not less than ten per cent milk fat and not less than 18.5 per cent total milk solids and must weigh not less than 4.5 pounds net per gallon. Allowance may be made for reduction in milk fat and total milk solids resulting from the addition of fruit, fruit juices, nuts and chocolate for flavoring. However, in no event may the product contain less than eight per cent milk fat, 16.5 per cent total milk solids and 1.6 pounds of total food solids per gallon, nor weigh less than 4.5 pounds net per gallon (H. B. 2308, approved March 20, 1950).

Milk.—A new **Georgia** law regulates the sale, inspection, importation and distribution of all fluid milk for human consumption—all milk and milk products shipped into the state from another state (S. B. 185, approved February 15, 1950).

New York stores (except those selling more than 3,000 pounds of milk in any month for off-premises delivery) making deliveries of milk for human consumption on the premises of hotels, restaurants, lunch counters, soda fountains or eating establishments, are no longer exempt from the licensing requirements of the milk control law (A. B. 525, approved April 1, 1950).

"Milk" and "cream" in **New York** are defined as "liquid milk and/or cream, fresh, sour or storage and/or condensed or evaporated whole milk or cream except when contained in hermetically sealed cans," for purposes of the size and marking requirements for bottles (S. B. 2678m, approved April 11, 1950).

Also in **New York,** whenever a milk dealer's license is denied or revoked, or an application for an original license or an extension of a license is denied, the Commissioner of Agriculture must notify the Division of Milk Control setting forth the basis for his denial or revocation (S. B. 408, approved April 8, 1950).

Narcotics.—A **New York** amendment provides that a person possessing, or having under his control, a preparation containing a narcotic drug, with intent to sell it, is guilty of a felony, punishable by imprisonment not to exceed ten years. Intent is presumptively established by proof that the person knowingly possessed or had under his control a total of two or more ounces of a preparation containing three per cent or more of the alkaloids heroin, morphine or cocaine, or sixteen or more ounces of a preparation containing opium, cannabis indica or any other narcotic drug. Computation is by avoirdupois ounces for solids or semi-solids and by fluid ounces for liquids. The presumption of intent is rebuttable (S. B. 2573, approved April 1, 1950).

Pest control.—A new law in California, effective May 1, 1950, requires pest control operators, who are engaged in crop dusting or spraying from airplanes, and against whom judgments for damages for improper operation have been rendered, to submit to the Director of Agriculture proof of financial responsibility in the form of a $25,000 deposit, surety bond, or insurance policy (A. B. 100-X, approved May 1, 1950).

Books

Widening Horizons

New Discoveries in Medicine: Their Effect on the Public Health. Paul R. Hawley. Columbia University Press, 2960 Broadway, New York 27, New York. 1950. 134 pages. $2.50.

This book is composed of the talks given by the author, the Director of the American College of Surgeons, in the second annual series of Bampton Lectures in America at Columbia University. After deciding upon the general theme of new discoveries in medicine and their effect on public health, it was Dr. Hawley's problem to select several discoveries which would be of interest to people not associated with biology, biochemistry, or vital statistics.

A discussion of the blood lent itself to a study of this nature: early discoveries, the development of blood transfusions as a therapeutic technique, the whole blood and plasma program of World War II, blood banks, and the Rh factor. He included a review of modern surgery of the heart and lungs: surgery of the heart, "blue baby" operations, and lung surgery in cancer and tuberculosis. In addition, modern prevention and treatment of mental disease including psychotherapy, shock therapy, and psychosurgery are surveyed.

The last section of the book is devoted to a discussion of the socio-economic aspects of medical care. The author traces the economic history of medical care to the present day when the quality of medical care has improved and the costs have increased substantially within a few years. Health prepayment plans grew and are growing to insure subscribers in the event of expensive hospitalization. The author, who is President of the Blue Cross Health Service, Inc., presents a very fair discussion of a pertinent problem: compulsory health insurance. Although he is admittedly opposed to such a measure, he has "no convictions that cannot be changed by competent evidence."

New Discoveries in Medicine is easily understandable to the layman as it is written in nontechnical language. Dr. Hawley obviously has much of interest to offer the reader. One could only wish that more such lucidly-presented subjects had been included in the book.

Man-to-Man Talks

The Future in Medicine. New York Academy of Medicine's "Lectures to the Laity" Series. Columbia University Press, 2690 Broadway, New York 27, New York. 1950. 160 pages. $2.50.

Everything eventually concerns medicine, because medicine enters into every human activity. But the lawyer, more than any other professional, must concern himself with medicine as a vital part of his business.

This book contains five essays, four by medical doctors, and one by a layman. They were presented as the 1949 program of the New York Academy of Medicine's series directed at the laity. The program has been conducted under the title "Lectures to the Laity" for fourteen years, but has actually been carried on since 1905.

Robert P. Patterson, former Secretary of War, is the one nonmedical writer, and he concerns himself with "Law and Medicine." He says, "It is true that the law has not caught up with science. When we reflect on the matter, we realize that law is bound to lag behind. The trouble comes when it lags too far behind. . . . The remedies for present defects are sometimes with the courts, but more often with the law-making legislatures. The lawyers have the duty of leadership in bringing

home to the people the need of changes in the law, to the end that public opinion may make its force felt both on the courts and on the legislatures. Then law suited only to the needs of earlier times may be eliminated, and the laws responsive to the needs of the present and the future may be passed." Mr. Patterson explores several important areas where the lawyer and the doctor meet. For instance, there is an inherent confusion between "insanity" and "criminal irresponsibility." There is the problem of the chronic alcoholic and the legality of committing such persons to institutions on the grounds of serving the common good. And there is the frequent contradiction in testimony given by apparently reliable "expert witnesses" who are medical doctors.

"The Endocrines: Servants or Masters?" is by Ephraim Shorr, Associate Professor of Medicine in Cornell University Medical College. Doctor Shorr is speaking to laymen, but his paper is a scholarly work, well documented, and well illustrated with charts and graphs. The influence of the ductless glands on growth and the various effects of their malfunction are covered briefly but clearly.

Leo Alexander, Director of the Neurobiologic Unit Division of Psychiatric Research, Boston State Hospital, writes on "Science Under Dictatorship." He traces the growth of the Nazi "medical" and "scientific" atrocities from the humble beginnings of permission to kill the "incurably" ill, to wholesale murder with many kinds of base motives. The socially unsuitable and finally the racially unsuitable died in great numbers. Doctor Alexander points out the heroic resistance of the doctors of Holland at the very beginning of their time under the Nazi control, and how successful they were in carrying on ethically.

The fourth piece, "Blood and Man," is by William C. Boyd, Associate Professor of biochemistry in Boston University School of Medicine. A history of man's knowledge of blood is tied closely to current developments and prospects for the future. The concept of race in terms of blood types, or in terms of "kind of blood" is examined and found wanting.

In the final essay, "The Criminal Within Us," the idea of "individual responsibility" is scrutinized in terms of our courts' treatment of both juvenile and adult delinquency. The writer, George E. Gardner, is Executive Director of the Judge Baker Guidance Clinic.

New York's Hospital Needs

A Pattern for Hospital Care, Final Report of the New York State Hospital Study. Eli Ginzberg. Columbia University Press, 2960 Broadway, New York 27, New York. 1949. 368 pages. $4.50.

Columbia University entered into a contract with the State of New York, through the Joint Hospital Survey and Planning Commission, to make a comprehensive study of hospital care in New York State. This book is the report on that study. But it is more than a report. A statement of problems in hospital care is intimately bound up with suggested methods of dealing with or eliminating those problems, in New York or in any other state. Accordingly, the book begins with recommendations directed at three agencies: the state, local government, and voluntary groups. The bulk of the book consists of the background and reasoning that lie behind these recommendations.

The state should:

Subsidize the expansion of service to ambulatory patients.

Expand state mental hospitals and make such improvements as raising salaries.

Raise the rate of reimbursing local governments for care given to tuberculosis patients.

Establish a State Hospital Commission in order to raise the quality of care, develop methods of determining hospital rates, and insure furthering the public interest in hospital operation.

Local government should:

Be more liberal about certifying older patients as public charges so they can have general hospitalization.

Subsidize a raise in the level of care given in homes for the aged.

Pay reasonable fees to voluntary hospitals that provide good services to ambulatory patients who are on the public assistance rolls.

In New York City, expand and improve facilities for tuberculosis patients, present facilities being very inadequate.

Reduce the pressure for free care in municipal hospitals by encouraging the increase of enrollment in hospital prepayment plans.

Voluntary groups should:

Improve the quality of hospital care by stricter control over the work of the hospital staff, and bring about effective management, implying that hospital administrators be given adequate power.

Make the facilities of voluntary hospitals available to all competent doctors instead of to a favored few.

Encourage the increase of enrollment in hospital prepayment plans.

Secure charitable contributions and spend them wisely in essential reforms and replacements.

Realize that no hospital can be self-sufficient, and therefore promote the coordination and integration of hospitals.

Can What You Can . . .

Outlines of Food Technology, by Harry W. von Loesecke. Reinhold Publishing Corporation, 330 West 42nd Street, New York, New York. 1949. 585 pages. $7.50.

Outlines of Food Technology is a comprehensive survey of modern food technology, a subject of interest to persons in or out of the food industry. The purpose of the book, in the author's words, ". . . is to outline the processes used in the modern food industry," a field becoming increasingly complex with the constant development of new improvements in food processing, new equipment, and new food products.

The author begins with a brief history of man's struggle to preserve his food successfully, together with the evolution of the Federal food and drug acts and Federal inspection. Following this introductory material, two modern answers to the food preservation problem are described: the tin can and the glass container.

The succeeding twelve chapters classify the various types of foods and food products—fruits, vegetables, dairy products, grains, and edible fats and oils, to name a few. The latest methods used to process and preserve a particular food and the product derived therefrom are outlined; in addition, the equipment, machinery, and packaging methods are described. To insure up-to-date coverage, more recent developments in food technology are treated, including the use of electronics in processing, the use of ethylene to speed the ripening of fruit, and the homogenization of milk. An entire chapter is devoted to the storage and marketing of fruits and vegetables, with attention given to the potentialities of increased air transportation.

What is perhaps the most recent development of the present-day food industry, preservation by freezing, is

delineated in the final chapter. In Mr. von Loesecke's words,

". . . there is no field of food technology today so teeming with conflicting thoughts as that of the preservation of foods by freezing. Under such conditions, it is nearly impossible to present this aspect of the subject in a satisfactory manner."

Nevertheless, the author has presented a comprehensive discussion of the several general methods of freezing and of particular foods, as well as a commentary on a technique first introduced in 1946, dehydrofreezing, which is moderate dehydration followed by freezing storage.

This is an easy-to-read and -understand book, due to the author's good organization of subject matter and to his brief but clear descriptions, sprinkled liberally throughout with photographs, diagrams, tables of chemical composition, formulas, and analytic comparisons of the various foods and processes.

As stated in the preface,

". . . the importance of food technology is becoming increasingly recognized by colleges and universities throughout the country, as evidenced by the fact that many of these institutions now have well organized food technology curricula. It is hoped that this book may serve a useful purpose in these courses of study."

However, *Outlines of Food Technology* should be a valuable reference book for the food industry lawyer and an educational treat for the layman, as well as an authoritative textbook for the food technology student.

Revised Liquor Regulations

Federal Malt Liquor Regulations 18, As Amended by Treasury Decision 5769. Commerce Clearing House, Inc., 214 North Michigan Avenue, Chicago 1, Illinois. 1950. 100 pages. $1.

Between the covers of this booklet is the complete text of the Fermented Malt Liquor Regulations, with all the changes made by the just-released Treasury Decision. The booklet presents far more than a simple statement of the revised regulation. Among the features is a side-by-side comparison of the sections of the regulations which are changed by the new decision. Subjects covered are the complicated problems that arise under federal regulation and control of the production, sale and tax payment of beer, lager beer, ale, porter and similar fermented beverages.

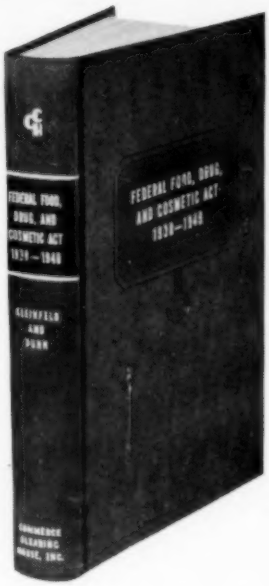
Antitrust Trends

A New Look at Antitrust Enforcement Trends. Commerce Clearing House, Inc., 214 North Michigan Avenue, Chicago 1, Illinois. 1950. 111 pages. $1.

This book brings together in full text the addresses delivered in the symposium held at the second annual meeting of the Section on Antitrust Law of the New York State Bar Association January 25 in New York City. The men who participated analyzed, criticized, and defended the changing trends in antitrust law theory.

Enforcement was intensified, and new theories were made the basis of proceedings by the Department of Justice and the Federal Trade Commission when Congress added the Robinson-Patman Price Discrimination Act to the already existing Sherman Act, Clayton Act, and Federal Trade Commission Act. New concepts of interpretation and application of the antitrust laws emerged in a steady stream of judicial pronouncements.

Those contributing to the text are practicing attorneys, legislators, economists, enforcement officials, and educational leaders. The discussions are salted with a wealth of citations to source material on antitrust law.



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Charles Wesley Dunn is Attorney at Law, Member of the New York Bar; Chairman, Division on Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law of American Bar Association; Chairman, Section on Food, Drug and Cosmetic Law, New York State Bar Association; Chairman, Editorial Advisory Board, *Food Drug Cosmetic Law Quarterly;* General Counsel for The Grocery Manufacturers of America, Inc., which is the National Association of the Food Industry; General Counsel of The American Pharmaceutical Manufacturers' Association; Professor of Law at New York University in Charge of Its Pioneer Postgraduate Courses on the Food, Drug and Cosmetic Law.

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